DOCTOR OF CLINICAL PSYCHOLOGY (DCLINPSY)

Doctorate in Clinical Psychology : Main Research Portfolio

1) The Role of Guilt and Shame in the Development and Maintenance of Perpetration-induced Posttraumatic Stress Disorder (PTSD); 2) Evaluating Service Need for a Patient Decision Aid Tool (PtDA) for Patients Considering Lung Transplantation in an NHS Cystic Fibrosis Service: An Assessment of Patients' and Clinician's Perspectives; 3) The Role of Health Anxiety in Mild Cognitive Impairment.

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Award date:
2017

Awarding institution:
University of Bath

Research Portfolio Submitted in Part Fulfilment of the requirements for the Degree of Doctorate in Clinical Psychology

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Doctorate in Clinical Psychology

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June 2017

Word Count

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Acknowledgements

I would like to start by thanking my research tutors, Paul Salkovskis, Liz Marks and Ailsa Russell, for their help and support with the research process. Your encouragement and guidance have meant that I now have three research projects that I can feel proud of and for that I am hugely grateful. An extra thank you to Ailsa for also being my Clinical Tutor, you have always been so understanding and containing. Thank you for taking the time to listen, for believing in me during times of self-doubt and for ensuring that I took some time for self-care once in a while.

Thank you to my external supervisors; Orazio Guiffrida, Samantha Phillips and Amanda Laffan. I am grateful for all of the time and support you have all given me with my research projects. Thank you too to Chloe Herrick who has been a huge source of support with my data collection. I am very grateful for the time and dedication you gave my research and for all the phonecalls and car journeys you made.

Thank you too to all of my placement supervisors. You have all provided me with great placements where I have learnt a huge amount. I consider myself to be extremely lucky to have had you all as supervisors and can honestly say that I have thoroughly enjoyed all of my placement experiences.

I would also like to take the time to thank all of the research participants who agreed to take part in my projects and the service users who so kindly agreed for me to write up our work as my case studies. I have learnt so much from each and every one of you as well as all of the other fantastic people I have worked with. It has been an absolute privilege to have been able to meet you all, to hear your stories and hopefully to have helped, if only a little. You have all certainly helped me become a better Psychologist for the work we did together.

A huge thank you to my wonderful cohort who truly are the best cohort ever. I could not ask for a better group of people to have trained alongside and I am so thankful to have been able to have shared this experience with you all. I never imagined I would make such amazing and lifelong friends during this process and whilst I am excited for this journey to continue, it will also feel such a loss to not see you all every week. You have been such a huge source of support, to know I have not been alone in this and have had 16 friends cheering me on every second of the way has been such a great feeling. I genuinely could not have done it without you all and have such a huge sense of shared cohort pride as we come to the end. We really have got this.

Another huge thank you to my family and my friends for being so patient and understanding whilst I have been much less available than I would like to have been over the last few months. Thank you all for believing in me when I doubted myself, for

managing my moods as they changed rapidly, for making sure I looked after myself in times of stress and worry, and for being so understanding when I didn't text back for weeks on end because my brain was too full. You all mean the world to me and I couldn't have done this without your continued love, support and understanding. I love you, feel so lucky to have you, and am so looking forward to being able to spend more time with you all again.

Last but by no means least, a special thank you to my wonderful fiancée Dan who has been as patient, thoughtful, caring and considerate as they come. I am sorry for all the times I have been grumpy and for the many times you have had to listen to me moan. Thank you for cooking me good food, for doing the washing up and for enforcing reasonable bedtimes. Thank you too for giving in to my pleas to fill our home with even more animals. They, and you, have kept me sane and for that I cannot thank you enough. I am very lucky to have had you by my side through all of this and for that I am grateful. Thank you, I love you.

Abstracts

Critical Review of the Literature Abstract

With an increasing recognition of non-fear based emotions in the development and maintenance of Post-Traumatic Stress Disorder (PTSD), attention has been drawn to the proposed central role of guilt and shame. Cognitive models of guilt-based and shame-based PTSD (Lee, Scragg & Turner, 2001) place emphasis on their role as mediating factors in the activation and development of guilt-based or shame-based schemas. Both guilt and shame have been suggested to be particularly pertinent emotions in perpetration-induced trauma; that is, the development of PTSD in response one's own actions. Whilst evidence supports the prevalence of perpetration-induced PTSD amongst offenders and in the military, amongst other professions; conclusions surrounding the proposed mediating role of guilt and shame in the relationship between perpetration trauma and the development of PTSD are yet to be drawn. This critical review consequently aims to investigate the proposed mediating role of guilt and shame in the development and maintenance of perpetration-induced PTSD. Results are discussed within the framework of Lee et al's cognitive model of guilt-based and shame-based PTSD, with early evidence suggestive of a role of guilt and shame in cognitive processes. Whilst evidence remains scarce, avenues for further research are discussed.

Keywords: Posttraumatic stress disorder; PTSD; perpetration-induced stress; shame; guilt; military; offenders

Service Improvement Project Abstract

Background. Lung transplantation is an established treatment option for many Cystic Fibrosis (CF) patients with advanced disease. Deciding whether to undergo transplantation is complex and services need to know how best to support patients and families. This study explores whether a Patient Decision Aid Tool (PtDA) could improve service provision in a UK NHS-based CF service.

Method. A focus group was conducted with 10 clinicians from an adult CF service. Three interviews were conducted, one with an individual patient and two with patient and family pairs. An Australian PtDA provided an example.

Results. The focus group and interviews were analysed separately utilising thematic analysis and then combined. Themes included meeting patient needs, accessibility, choice, communication, feeling prepared and developing the tool.

Conclusions. A PtDA for lung transplantation was suggested to be beneficial. In spite of some challenges, it was felt to offer a number of improvements to service provision in an NHS CF service.

Keywords: Cystic fibrosis; CF; lung transplant; patient decision aid tool; PtDA

Main Research Project Abstract

Objectives. Mild cognitive impairment (MCI) is a common yet controversial diagnosis with marked heterogeneity in its' diagnostic criteria and clinical outcomes. This heterogeneity brings with it uncertainty and ambiguity for both the clinicians working in memory services as well as the individuals who receive this label. This study aims to investigate the extent and role of health anxiety in individuals' experiences of MCI, evaluating the impact of health anxiety (HA) on quality of life (QoL), perceived ability and health beliefs.

Methods. Forty-five individuals with MCI completed questionnaires assessing HA, QoL, mood, functional ability and health beliefs. They also completed two cognitive tasks followed by self-ratings of perceived performance and attribution of their performance to MCI. Groups were compared based on their level of HA (low vs. high) and to a sample of non-impaired controls (n = 17).

Results. The high HA group reported significantly reduced QoL as compared to the low HA group and healthy controls. No significant effect of HA was found on perceived performance or attribution of performance to MCI. Further exploratory analyses found significant mediational effects of depression and level of objective impairment on QoL, level of objective impairment on perceived performance, and generalised anxiety on health beliefs.

Conclusions. In addition to a significant relationship between health anxiety and QoL in individuals with MCI, there is an important role for depression and level of objective impairment.

Keywords: Mild cognitive impairment; MCI; health anxiety; quality of life; depression

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Critical Review of the Literature

The Role of Guilt and Shame in the Development and Maintenance of Perpetration-induced Posttraumatic Stress Disorder (PTSD)

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Date: June 2017

Word Count: 6,678

Proposed Journal for Publication: Clinical Psychology Review

Introduction

Guilt, Shame and Posttraumatic Stress Disorder (PTSD)

Unlike other anxiety disorders, posttraumatic stress disorder (PTSD) is unique in its aetiology in the specification of the presence of an associated 'event' (i.e. a trauma) in its diagnostic criterion. Earlier conceptualisations of PTSD placed emphasis on the role of fear-based emotion in response to the traumatic event. However, recent revisions to diagnostic criteria have recognised the increasingly documented role of non-fear emotions in the development and maintenance of PTSD, including shame, guilt, anger and disgust (Lee, Scragg, & Turner, 2001).

Consequently, the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders, DSM V, (APA, 2013) removed the diagnostic specification of the peritraumatic response in PTSD as being characterised by "*intense fear, helplessness or horror*". Given evidence of a broader spectrum of emotional complexity in PTSD, defining the emotional response was deemed inappropriate (APA, 2013). However, this is not wholly supported with suggestions that it inappropriately broadens what can be deemed 'traumatic', serving only to further a conceptual 'bracket creep' (Spitzer, First, & Wakefield, 2007).

Although once used interchangeably, guilt and shame are now recognised as distinct emotional states (Tangney, Miller, Flicker, & Barlow, 1996). Guilt is commonly defined as negative feelings towards a past action or behaviour with a focus on remorse and reparative action; whilst shame is suggested to be characterised by a more global negative evaluation of the self often associated with concealment and escape (Tangney & Dearing, 2002; Tangney, 1996).

Guilt and shame have been proposed to be important emotional states in PTSD (McLean & Foa, 2016), and found to influence severity (Leskela, Dieperink, & Thuras, 2002; Owens, Steger, Whitesell, & Herrera, 2009; Street & Arias, 2001) and treatment response (Kubany et al., 1995; Owens, Chard, & Ann Cox, 2008). Guilt in PTSD has been linked to the need for and possibility of restorative action. Kubany (1998) suggests that greater emotional distress can arise when the person's need to repair is blocked, driving a number of avoidance behaviours (e.g. alcohol, isolation) as a means of escape. Kubany and Manke (1995) also highlight a cognitive role of guilt centred around appraisals of responsibility, lack of justification and perceived violation of moral standards.

Further distinctions have been made between the experiences of shame in PTSD as internal versus external (Gilbert, 1998); internal shame being defined as the person's view about themselves whilst external shame refers to the belief that other people perceive you as being inferior or damaged (akin to social anxiety (Clark & Wells, 1995). Both have been argued to occur either separately or co-morbidly, in the individuals' appraisal of the traumatic event (Lee et al., 2001). In addition, shame has also been suggested to occur as both a primary (i.e. peritraumatic; Nathanson, 1994) and secondary (i.e. post-trauma appraisals; Ehlers & Steil, 1995) emotion in PTSD.

With evidence supporting the relationship between PTSD and both shame (Andrews, Brewin, Rose, & Kirk, 2000; Leskela et al., 2002) and guilt (Joseph, Hodgkinson, Yule, & Williams, 1993; Kubany et al., 1996), Lee et al (2001) proposed a bi-directional cognitive model of guilt-based and shame-based PTSD (Figures 1.1 & 1.2). Akin to Ehlers and Clark's (2000) well established cognitive model of PTSD, Lee et al (2001) emphasise the role of trauma appraisals in the development and maintenance of shame-based and guilt-based PTSD. Specifically, at the centre of Lee et al's (2001) model is the congruence or incongruence of the person's trauma appraisals with their pre-existing schemas. They propose the same mechanism for both emotions, with the difference in emotional response lying in the evaluation of meaning (i.e. whether appraisals are guilt-based or shame-based). Specifically, shame and/or guilt are proposed to occur when the evaluated meaning of the trauma event is either *congruent* with pre-existing, latent shame or guilt-based schemas which are activated by the trauma appraisals, or *incongruent* with a pre-existing positive self-schema. When congruence occurs, the trauma appraisals serve to confirm a *pre-existing* negative schema attributed to the self. When incongruence occurs, the result is the formation of *new* shame or guilt-based beliefs.

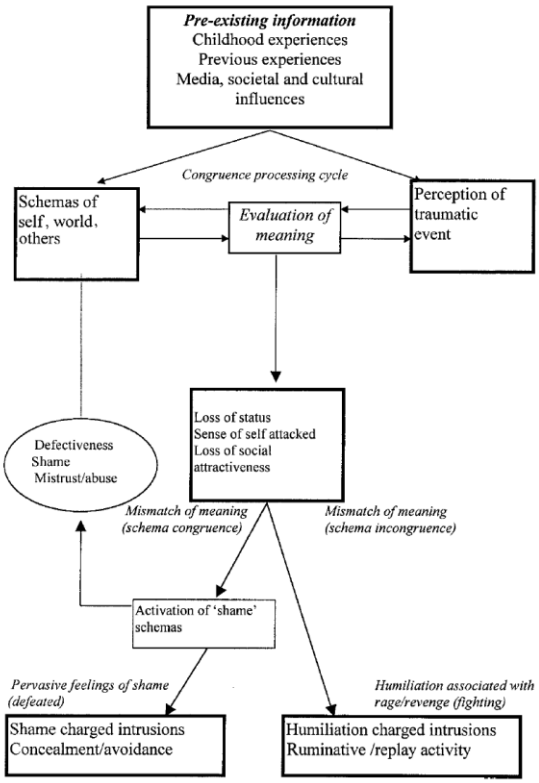

Figure 1.1: Cognitive Model of Shame-based PTSD (Lee et al, 2001)

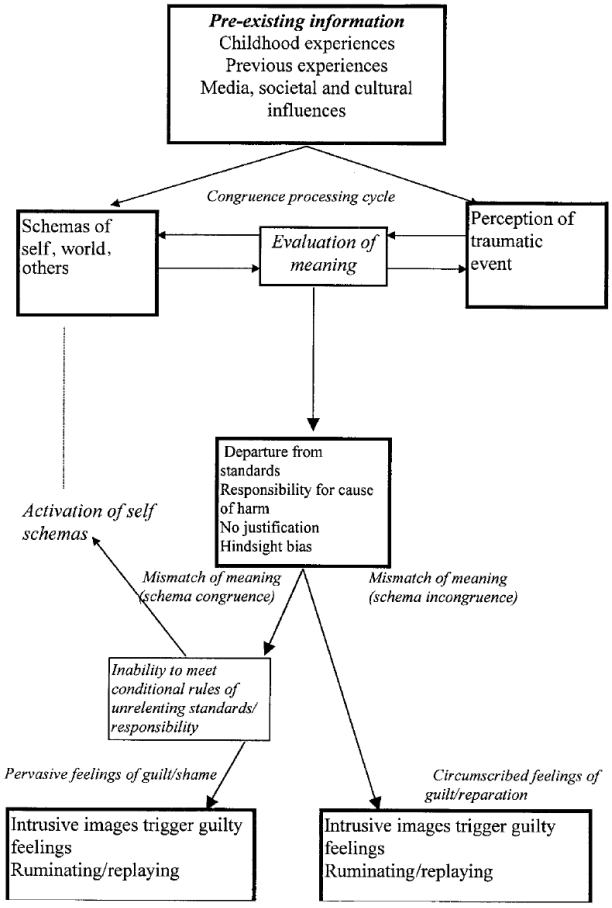

Figure 1.2: Cognitive Model of Guilt-based PTSD (Lee et al, 2001)

Clinically, it has been suggested that without addressing shame and guilt when they are present, the efficacy of PTSD interventions is impeded (Pitman et al., 1991; Resick & Schnicke, 1992; Riggs, Dancu, Gershuny, Greenberg, & Foa, 1992). Contrastingly, direct targeting of guilt and shame in therapy has been suggested to improve risk assessment and effectiveness of PTSD interventions (Bryan, Morrow, Etienne, & Ray-Sannerud, 2013).

PTSD and the perpetration of harm

The concept of the 'self-traumatised perpetrator' (Young, 2002) arose from relatively early experimental research on PTSD in the military in the 1970s. Lifton (1973) spoke of a number of Vietnam veterans experiencing severe PTSD as a consequence of atrocities they committed against non-combatants, highlighting the potential for one's own actions to act as a trauma. However, in spite of this early recognition, focus has largely remained on victims in PTSD.

It is broadly accepted that the action of killing or harming another could act as a traumatic stressor for the person committing the act. What is at issue, however, is that the very nature of PTSD in identifying a 'victim' and a 'perpetrator' makes blame inherent, thus involving political and moral value judgement processes (McNally, 2010). For example, in response to the recognition that killing in war resulted in PTSD in those ordered to commit such acts, the presented 'solution' was to shift blame to the government, thus allowing individuals to once again be perceived as the victims of a bigger enemy (Fassin & Rechtman, 2009). Consequently, the scarcity of research in this area has been argued to be a matter of inattention rather than one of dispute (MacNair, 2015).

In broadening the diagnostic criterion surrounding what constitutes a 'traumatic event', the DSM-5 (APA, 2013) allows for perpetration to be classified as a trauma through the specified experience of "direct exposure" to death or harm. Although not named explicitly, in the accompanying discussion reference is also made to the act of "killing the enemy" as a potential source of trauma in the military. However, more explicit recognition is argued as warranted given a growing body of evidence of 'perpetration-induced trauma' in a multitude of populations beyond the military (MacNair, 2015).

PTSD and moral injury in the military

The role of non-fear emotions in PTSD has been emphasised in the military as a consequence of the nature of combat-related trauma. Specifically, this type of trauma is often associated with ethical and moral transgressions, including perceived acts of betrayal (e.g. being unable to save a comrade; leadership failure), 'survivor guilt', and the perpetration of violence or killing when following orders (Drescher et al., 2011). Such moral transgressions have been found to be equally likely to elicit guilt and shame (Tangney et al., 1996).

Combat-related harm, particularly killing, has been recognised as a significant risk factor for PTSD in serving personnel (Stern, 2014). Veterans who have actively killed experience higher rates and severity of PTSD in comparison with those who have witnessed death (MacNair, 2002) and are at a higher risk of dissociation, functional impairment, aggression, violence, relationship problems and alcohol abuse (Maguen et al., 2010; Maguen et al., 2009). The risk of PTSD increases further in cases where a non-combatant is killed, especially if female, a child or elderly (Maguen et al., 2013; Maguen et al., 2009). Within a context of the evolving nature of war, which is now frequently characterised by an unmarked enemy and civilian threats, the risk and prevalence of perpetration-induced PTSD in service personnel is likely to only continue to grow.

The concept of 'moral injury' has arisen in the military literature; originally coined by Litz et al (2009) and defined as "*the enduring consequences of perpetrating, failing to prevent, bearing witness to, or learning about acts that transgress deeply held moral beliefs and expectations*" (Nash & Litz, 2013), p.368). Associated thoughts and feelings of shame, guilt and self-loathing have all been suggested to be characteristic (Drescher et al., 2011) with Litz et al (2009) placing shame and guilt as central emotions in their social-cognitive model. In line with Lee et al's (2001) cognitive model of shame-based and guilt-based PTSD, Litz et al (2009) place emphasis on the relationship between pre-existing beliefs about the self and trauma appraisals. In addition, they too highlight the relationship between these cognitive processes, feelings of guilt and/or shame and symptoms of PTSD, including intrusions, numbing, avoidance and withdrawal.

Perpetration-induced PTSD in offenders

MacNair's (2002) concept of 'perpetration-induced' PTSD has also been extended into the field of offence-related trauma in forensic populations. It has been argued that crimes such as homicide and interpersonal violence can lead to PTSD (Lawrence & Taft,

2013; Papanastassiou, Waldron, Boyle, & Chesterman, 2004) and high rates of perpetration-induced trauma have been identified in both prisons and secure mental health units (Friel, White, & Hull, 2008). Estimated prevalence rates have varied, with reported rates falling between 15 – 58% (Papanastassiou et al., 2004; Payne, Watt, Rogers, & McMurran, 2008; Pollock, 1999; Spitzer et al., 2001). Spitzer et al (2001) found that in a population of 53 mentally ill offenders, the perpetrated offence was the second most common trauma causing PTSD after childhood sexual abuse.

More recently, the role of perpetration-induced PTSD has also been suggested as applicable to gang membership (Kerig, Chaplo, Bennett, & Modrowski, 2016), due to acts of violence often being committed either as rites of passage, turf wars or as part of ongoing gang-related activity (Alleyne & Wood, 2012; Klein & Maxson, 2010; Taylor, Peterson, Esbensen, & Freng, 2007). Following the identified relationship between child soldiering and perpetration-induced PTSD (Betancourt, Newnham, McBain, & Brennan, 2013; Klasen, Reissmann, Voss, & Okello, 2015), Kerig et al (2016) investigated this relationship in adolescent gang members and found that perpetration-induced violence predicted the variance in posttraumatic symptoms above and beyond trauma exposure among other factors.

Aims of the review

This review aims to explore the proposed relationship between PTSD, 'perpetration' as trauma, and feelings of guilt and/or shame. In reviewing the relevant literature, the proposed mechanism of guilt and shame as mediating factors will be explored. Any additional factors explored in the relevant studies that may mediate this relationship will also be discussed. Based upon a model of mediation which proposes that the independent variable influences a mediating factor, which in turn mediates the dependent variable, mediation is determined via the degree to which the direct relationship between the independent variable and dependent variable is reduced by the inclusion of the mediating factor (Baron & Kenny, 1986).

The results will then be considered within the context of the afore mentioned theoretical model of shame-based and guilt-based PTSD (Lee et al., 2001). Whilst the term 'perpetration' may often be associated more with offenders, it is defined as a person who commits an illegal, harmful or immoral act; as such, the term is used more broadly throughout this review to encompass any act of harm which is committed by one person against another.

Methodology

Design

Given that research in this area remains relatively scarce, there are insufficient high-quality research studies for a systematic review or meta-analysis to be completed. In addition, studies are collated across differing population groups and utilise an assortment of measures to explore the mechanisms central to this review, making direct comparability of measures across studies unfeasible. As such, this review conducts a systematic within a narrative synthesis of the literature.

This critical review of the literature aims to answer the following question:

- Is there a mediating role of guilt and shame in the development and maintenance of perpetration-induced PTSD?
- Is there any evidenced association with the cognitive variables (i.e. schema congruence/incongruence, cognitive appraisals of trauma, evaluation of meaning) central to Lee et al's model of shame-based and guilt-based PTSD?

Inclusion/Exclusion criteria

The following inclusion criteria was applied to the literature search:

1. Publications must be written in English due to a lack of translation options.
2. The population must all have perpetrated acts of harm, be classified into separate groups according to their trauma type (one of which must be perpetration relevant) or a measure of the degree of involvement in perpetrated acts must be utilised.
3. Measures of PTSD and of guilt and/or shame must be included.
4. The relationship between guilt and/or shame, perpetration and PTSD must be the focus of the study.
5. The study must explore the mediating role of guilt/shame within the relationship of perpetration & PTSD.
6. Participants must be adults (≥18 years).

Search Method

Potential studies to be included were identified via a search of five electronic academic literature databases: PsycInfo, Pubmed, Embase, Cochrane and Google Scholar. The following terms were included in the search strategy:

"PTSD" OR "posttraumatic stress" OR "post traumatic stress*" OR "post traumatic stress disorder" OR "posttraumatic stress disorder" OR "traumatic stress" OR "perpetration-induced traumatic stress" AND "shame" OR "guilt" AND "combat" OR "perpetrat*" OR "violence" OR "kill*" OR "profess*" OR "offend*" OR "offence"*

A total of 642 articles were returned and were exported to covidence.org which was utilised as an online reviewing tool. After removal of duplicates (n = 15) and those screened out by title or abstract (n = 526), 103 articles were reviewed at the level of full text screening. A further 92 studies were removed at this stage (see Figure 1.3 for details), leaving 11 articles to be included in the review. Reference lists were also checked and did not identify any additional studies to be included.

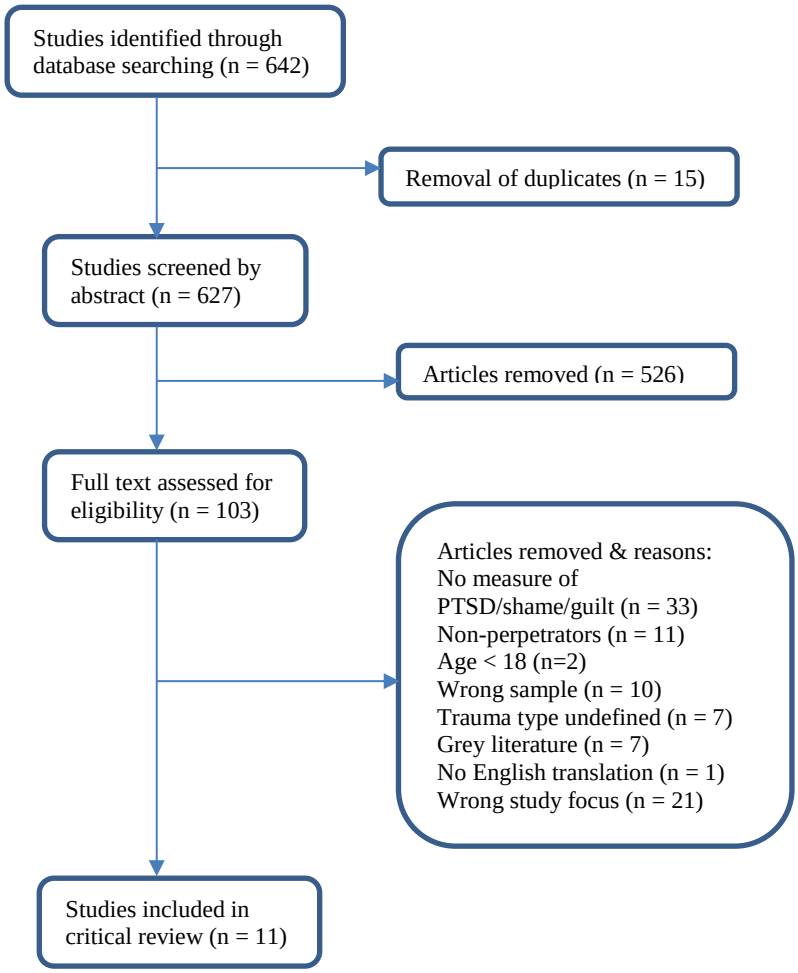

Figure 1.3: Flowchart of literature review search strategy

Data Extraction

The following data was abstracted from each study; sample size and population, including the defined perpetration-based trauma; measures of PTSD, shame/guilt plus any

additional variables; type of analysis used; results detailing the relationship between PTSD, perpetration and guilt/shame including any mediating relationship; and results detailing any relationship with the cognitive variables outlined in Lee et al's (2001) model. See Table 1.1 for a summary.

Table 1.1: Summary of Studies included in the Review

Author & Year	Sample size, population & measure of perpetration	PTSD measure	Guilt/Shame Measure	Other Measures	Analysis used	Results (reported those involving PTSD, guilt/shame, perpetration)
Stein et al (2012)	122 active duty service members diagnosed with PTSD (US military). Heterogenous trauma types across sample; focus on those traumas classified by authors as 'Moral Injury by Self' (MIS) (i.e. having killed or harmed another) reported by 12% of sample.	PTSD Symptom Scale, Interview Version (PSS-I) (Foa, Riggs, Dancu & Rothbaum, 1993)	*Guilt* Trauma-related Guilt Inventory (TRGI; Kubany et al, 1996)	*Peri/Post Trauma Emotions* Peritraumatic & posttraumatic emotions questionnaire (PTEQ) (Resick, 1986; Resick, Jordan, Girelli & Hutter, 1988) *Anxiety* Beck Anxiety Inventory (BAI) (Beck, Epstein, Brown & Steer, 1988) *Depression* Beck Depression Inventory (BDI-II) (Beck, Steer & Brown, 1996) *Post-trauma appraisals* Posttraumatic Cognitions Inventory (PTCI) (Foa, Ehlers, Clark, Tolin & Orsillo, 1999)	Point-biseriel correlations Exploratory regressions	MIS and posttrauma reactions: Humiliated ($r = 0.21$), Sad ($r = 0.26$), Numb ($r = 0.26$), $p = <0.05$ for all MIS significant predictor of: TRGI Hindsight-bias/responsibility ($\beta = 0.39$, $p = 0.003$); TRGI Wrongdoing ($\beta = 0.26$, $p = 0.043$); PSS-I re-experiencing subscale ($\beta = 0.28$, $p = 0.015$); PTCI negative cognitions about the self, marginal result ($\beta = 0.26$, $p = 0.056$)

				Anger State-Trait Anger Expressions Inventory (STAXI) (Spielberger, 1988)		
Currier, Holland, Jones & Sheu (2014)	Data from 1,203 Vietnam veterans who participated in National Vietnam Veterans Readjustment Study (NVVRS) (US military). Perpetration measured via measure of involvement in abusive violence rated on 6-point Likert scale (range from 0 = *not at all* to 6 = *I was responsible*)	Predicted probability index of PTSD; Diagnostic Interview Schedule (DIS) symptom count & Mississippi Combat Scale (MCS; Keane, Caddell & Taylor, 1988)	*Guilt* 3-item forced choice ('yes' or 'no') measure of guilt.	*Drug Use* 2-item forced choice ('yes' or 'no) measure with diagnostic variables from DIS *Alcohol Use* 2-item forced choice ('yes' or 'no) measure with diagnostic variables from DIS *Suicidality* 2-item forced choice ('yes' or 'no) measure with diagnostic variables from DIS	Structural equation modelling	Degree of involvement in abusive violence (independent variable) significant direct effect on PTSD ($\beta = 0.15$, $p < 0.001$) & guilt ($\beta = 0.19$, $p < 0.01$) as mediating factor. Direct effect on PTSD and guilt as co-mediating factors ($\beta = 0.44$, $p < 0.001$). Model provided good fit to the data $\chi^2(151) = 196.79$, $p = 0.007$.

Shea, Presseau, Finley, Reddy & Spofford (2016)	206 National Guard and Reserve Unit Veterans who had deployed to Iraq or Afghanistan (US military). Heterogenous trauma type in sample; for purpose of this review focus on those classified as 'having killed' (n = 26); divided into 'killed the enemy' (n = 23) & 'killed a non-combatant' (n = 3).	Clinician administered PTSD for DSM-IV (CAPS-IV; Blake et al, 1995).	*Guilt* Sum of two CAPS-IV items that assess guilt.	*Mood* Brief Symptom Inventory (BSI; Derogatis & Melisaratos, 1983)	Multivariate multilinear regression (Stevens, 2002)	No significant relationship between guilt and BSI symptoms. Relationship between having killed and guilt also not supported. Relationship between having killed and severity of PTSD symptoms also not supported.

Beckham, Feldman & Kirby (1998)	151 help-seeking Vietnam veterans in an outpatient PTSD clinic (US military). Perpetration classified through a six-item subscale from the Vietnam Era Stress Inventory (Wilson & Krauss, 1983) as a measure of involvement in atrocities.	Mississippi Scale for Combat-related PTSD (MSC; Keane et al, 1989); Clinician-administered PTSD Scale Diagnostic version (CAPS; Blake et al, 1995); Davidson Trauma Scale (DTS; Davidson et al, 1997).	*Guilt* Trauma-related Guilt Inventory (TRGI; Kubany et al, 1996)	*Degree of combat exposure* Combat Exposure Scale (CES; Keane, Caddell, & Taylor, 1988) *Index of interpersonal violence* Overall Violence Index (OVI), a subscale of Conflict-Tactics Scale (CTS; Straus, 1979).	Spearman correlations Multiple hierarchal regression analyses	Atrocities exposure significantly related to TRGI Global ($r = 0.34$), TRGI Distress ($r = 0.24$), TRGI cognitions ($r = 0.23$), TRGI hindsight bias/responsibility ($r = 0.2$) & TRGI wrongdoing ($r = 0.33$); all *p*s < 0.05). Atrocities exposure not related to TRGI lack of justification ($p > 0.05$). Atrocities significantly related to overall PTSD severity ($\beta = 0.54 – 0.82$); symptoms of avoidance & emotional numbing ($\beta = 0.34$); TRGI overall guilt ($\beta = 0.04$); TRGI guilt cognitions ($\beta = 0.03$); TRGI hindsight bias/responsibility ($\beta = 0.03$); and TRGI wrongdoing ($\beta = 0.01$), all *p*s < 0.05.

Hendin & Pollinger Haas (1991)	100 Vietnam veterans (US military). Type of perpetration trauma classified by self-report from interview and investigated in post-hoc analyses to determine if nature of trauma differentiated the two groups.	Revised Combat Scale (Egendorf et al, 1981), a checklist of PTSD symptoms based on the DSM-III diagnostic criteria & clinical interviews.	*Guilt* Coded data from clinical interviews: split into 'guilt about combat actions' and 'survivor guilt'.	*Measures of suicide attempts & suicidal ideation* Coded data from clinical interviews. *Peritraumatic emotions* Coded data from clinical interviews.	Chi-square tests with Yates' corrections	Guilt about combat actions significant in veterans who committed suicide attempts ($\chi^2 = 14.24$, df = 1, $p < 0.001$) but not in nonsuicidal veterans. Guilt about combat actions significant in veterans with suicidal ideation ($\chi^2 = 3.71$, df = 1, $p = 0.005$). Significant association with peritraumatic feelings of "out of control" in suicide attempters with greater involvement in atrocities ($\chi^2 = 9.84$, df = 1, $p = 0.002$).
					Forward stepwise logistic regression	Guilt about combat actions (β=9.16) and depression (β=1.95) as two significant predictors in suicide attempt model ($p < 0.05$). Guilt about combat actions ($\beta = 1.45$) s

						significant predictor in suicidal ideation model.
Dennis et al (2016)	603 help-seeking combat Vietnam veterans (US military). Perpetration was classified through a six-item subscale from the Vietnam Era Stress Inventory (Wilson & Krauss, 1983) as a measure of involvement in atrocities.	Davidson Trauma Scale (DTS; Davidson et al, 1997).	*Guilt* Trauma-related Guilt Inventory (TRGI; Kubany et al, 1996)	*Depression* Beck Depression Inventory (BDI-II) (Beck, Steer & Brown, 1996) – single item as a measure of suicidal ideation & remaining 20 items as a measure of depression. *Hostility* Cook-Medley Hostility Scale (Cook & Medley, 1954). *Interpersonal violence* Violence subscale of the Conflicts Tactics Scale (CTS; Strauss, 1979). *Combat Exposure* Combat Exposure Scale (CES; Keane, Caddell, & Taylor, 1988)	Spearman's rank correlations. Path analysis. Bootstrapped confidence intervals to test mediation of indirect effects.	All measures of guilt on TRGI correlated significantly at $p < 0.05$ with PTSD severity and involvement in atrocities. Significant ($p < 0.05$) identified direct pathways: Atrocities → Guilt → PTSD ($\beta = 0.20$) Significant ($p < 0.05$) identified indirect pathways: Combat exposure → Atrocities → Guilt → PTSD ($\beta = 0.07$); Atrocities → Guilt → PTSD → Hostility ($\beta = 0.2$); Combat Exposure → Atrocities → Guilt → PTSD → Hostility ($\beta = 0.2$);

Huang & Kashubeck-West (2014)	289 Afghanistan or Iraq Veterans recruited through online veteran organisations (US military). Perpetration measured via measure of agency: Atrocities Exposure subscale of DRRI, expanded to include 16 additional items related to direct perpetration of atrocities.	PTSD Checklist (PCL; Weathers, Litz, Herman, Huska, & Keane, 1993)	*Guilt* Laufer-Parson Guilt Inventory (LPGI; Laufer & Frey-Wouters, 1988)	*Combat exposure* Adapted version of Combat Experiences subscale (removal of agency questions) from the Deployment Risk and Resiliance Inventory (DRRI; King et al, 2003). *Exposure to aftermath of war* Post Battle Experiences subscale of DRRI. *Exposure to atrocities* Adapted Atrocities Exposure (removal of agency questions) subscale of DRRI. *Perceived Threat* Perceived Threat subscale of DRRI.	Correlations Hierarchical regression analyses Bootstrapping	*Agency, PTSD & Guilt* Significant positive correlations were found between all 3 variables. Guilt accounted for 16% of variance over and above exposure (0.4%), perceived threat (0.3%) & agency (0.02%). Age ($\beta = 2.84$) & guilt ($\beta = 14.06$) remained significant predictors of PTSD. Guilt shared variance with exposure, agency and perceived threat. Guilt had a significant mediation effect between exposure & PTSD (indirect effect of 1.34, 99% CI, $p < 0.001$); between perceived threat & PTSD (indirect effect of 0.96, 99% CI, $p < 0.01$); & between agency & PTSD (indirect effect of 3.62, 99% CI, $p < 0.001$)

Jordan, Eisen, Bolton, Nash & Litz (2017)	867 active duty Marines previously deployed to Iraq or Afghanistan. Perpetration measured by 'transgression' subscale of Moral Injury Event Scale (MIES; Nash et al, 2013).	Posttraumatic Stress Disorder Checklist (PCL; Weathers, Litz, Herman, Huska & Keane, 1993).	*Guilt and Shame* Positive and Negative Affect Schedule (PANAS; Watson, Clark & Tellegan, 1988) – adapted to measure emotions of 'Ashamed' and 'Guilty' through a combined measure of both.	*Combat exposure* Combat Experiences Scale (CES) from the Deployment Risk and Resiliance Inventory (DRRI; King et al, 2003). *Peritraumatic dissociation* Peritraumatic dissociative experiences questionnaire (PDEQ; Marmar, Weiss & Metzler, 1997) *Betrayal* Subscale of MIES. *Anger* Adaptation of PANAS as per guilt and shame.	Correlations Structural equation modelling	Perpetration, guilt/shame and PTSD severity correlated positively with each other (p's < 0.065) <u>Significant direct effects</u>: perpetration on guilt/shame ($\beta = 0.26$, $p < 0.05$); guilt/shame on PTSD ($\beta = 0.23$, $p < 0.01$) <u>Marginal significant indirect effects</u>: perpetration $\rightarrow$ guilt/shame $\rightarrow$ PTSD ($\beta = 0.09$, $p = 0.08$); Model provided good fit to the data $\chi^2(239, 526) = 538.55$, $p < 0.001$

Marx et al (2010)	1,323 Vietnam veterans taking part in a large scale study (US military). Perpetration assessed by War Stress Inventory (WSI; Rosenheck & Fontana, 1989)	Structured Clinical Interview for DSM-III-R (SCID; Spitzer, Williams, Gibson & First, 1989)	*Guilt* Laufer-Parsons Inventory (Laufer, Yager, Frey-Wouters & Donnellan, 1981)	*Depression* Structured Clinical Interview for DSM-III-R (SCID; Spitzer, Williams, Gibson & First, 1989) *Combat Exposure* Combat Exposure Scale (CES; Keane, Caddell, & Taylor, 1988)	Pearson's r correlations Path analysis	All correlations amongst variables significant at $p < 0.01$ level. <u>Significant indirect effects</u>: Participating in abusive violence exerted an indirect effect on both PTSD (effect = 0.20, $p < 0.001$) & MDD (effect = 0.12, $p < 0.001$) via combat related guilt. Magnitude of indirect effect nearly 2x greater for PTSD than MD; minimal overlap in 95% CI (.31 - .52 PTSD; .16 - .32 MDD). Variance explained by model: 52% PTSD & 17% MDD.

Crisford, Dare & Evangeli (2008)	45 'mentally disordered offenders' from an inpatient secure unit (UK). *Perpetration* All participants had committed an offence of a violent or sexual nature and had admitted the offence. Independent ratings of severity made by researcher plus 2 clinicians & mean of 3 independent ratings taken as final rating of severity.	Detailed Assessment of Posttraumatic Stress (DAPS; Briere, 2001).	*Guilt* Trauma-Related Guilt Inventory (TRGI; Kubany, 2004)	*Positive and Negative Affect* Positive and Negative Affect Scale (PANAS; Watson, Clark & Tellegen,1988)	Correlations Independent t tests Hierarchical regression analysis	Guilt correlated significantly with PTSD only (r = 0.43). Significant difference in guilt scores between known vs. unknown victims (t(41) = 2.03, p = 0.05). Greater guilt with unknown victims. Guilt (β = 0.34) significantly increased variance from 43% to 54% (F(1, 38) = 9.02, p = 0.05) in predicting trauma symptomology. Negative affect (β = 0.384) and offence severity (β = 0.271) were also significant in the model (p < 0.05)

Sippel & Marshall (2011)	47 individuals currently in a couple where interpersonal violence has been identified in the relationship (USA). Perpetration via interpersonal violence measured via the Revised Conflicts Tactics Scale (CTS2; Straus, Hamby, Boney-McCoy & Sugarman, 1996)	Clinician-administered PTSD Scale Diagnostic version (CAPS; Blake et al, 1995)	*Shame:* *Processing bias* Computerised emotional Stroop task – supraliminal (word displayed until vocal response) & subliminal (word masked after set time & mask displayed until response). *Shame schemas* Self-referential encoding task – indicate whether shame words describe self by 'yes' or 'no' response	None	Mediation models – Preacher & Hayes' (2004) bootstrapping methods	<u>Significant direct effects:</u> PTSD severity on subliminal shame processing speed ($\beta = -0.35$, $p < 0.05$); subliminal shame processing speed on IPV perpetration frequency ($\beta = -0.37$, $p < 0.05$); PTSD on supraliminal shame processing ($\beta = -0.29$, $p < 0.05$) <u>Significant indirect effects</u>: Mediation effect of subliminal shame processing speed in the effect of PTSD severity on IPV perpetration (M = 0.0058, SE = 0.0054, 95% CI = 0.0048 – 0.0165). Partial mediation effect of subliminal shame processing speed in the effect of PTSD severity on IPV perpetration (M = 0.0004, SE = 0.0033, 95% CI = 0.0003 – 0.0060).

Results

Overview of studies

The selected studies explored the relationship between perpetration-induced PTSD and shame and/or guilt across two populations: military personnel/veterans and violent/sexual offenders. All studies were reviewed in terms of the mediating effect of feelings of guilt or shame in the relationship between perpetration as a trauma event and PTSD. Table 1.1 provides a summary of all the studies included and the key findings.

Characteristics of the studies

Military studies

Nine of the reviewed papers focussed on the military. All studies were conducted in the United States. Two of the papers explored actively serving soldiers whilst the remaining seven explored veterans. Five studies recruited veterans from the Vietnam war whilst three recruited veterans who had been deployed to Afghanistan or Iraq. All studies utilised a cross-sectional design. None included a control group. Sample sizes ranged from 23 to 1,323. Samples were drawn from large research cohort studies of military personnel (Currier, Holland, Jones, & Sheu, 2014; Jordan, Eisen, Bolton, Nash, & Litz, 2017; Marx et al., 2010; Stein et al., 2012), post-deployment health assessments (Shea, Presseau, Finley, Reddy, & Spofford, 2016), outpatient PTSD clinics (Beckham, Feldman, & Kirby, 1998; Dennis et al., 2017), military hospitals (Hendin & Haas, 1991), and online recruitment via veteran organisations and professionals working with veterans (Huang & Kashubeck-West, 2015). Identified acts of perpetration covered combat-related actions such as killing or harming the enemy, as well as involvement in additional war-related "atrocities" such as killing or harming non-combatants, torturing prisoners or mutilating dead bodies. Eight of the nine identified studies focused on the role of guilt alone, whilst the remaining study utilised a combined measure of both guilt and shame.

Offender populations

Two of the reviewed papers focussed on offenders. Studies were conducted in the United States (n = 1) and the United Kingdom (n = 1). One study included violent and sexual offenders (Crisford, Dare, & Evangeli, 2008) whilst the other utilised a community sample of couples with a history of interpersonal violence (Sippel & Marshall, 2011). Both utilised a cross-sectional design. Neither included a control group. Sample sizes ranged from 45 to 47. Samples were drawn from a secure unit (Crisford et al., 2008) and through a larger scale research trial (Sippel & Marshall, 2011). Identified acts of perpetration included violent and sexual offences (Crisford et al., 2008) and non-

criminalised interpersonal violence (Sippel & Marshall, 2011). Crisford et al (2008) focused on the role of guilt, whilst Sippel and Marshall (2011) focused on the role of shame.

Measures

Measures of PTSD

Eleven different measures were used as a means of quantifying the severity of PTSD. Two studies utilised multiple measures. Currier et al (2014) used two measures; the first was a predicted probability index of PTSD, derived by the researchers through logistic regression using a symptom count and adjustment measures from a Diagnostic Interview Schedule (DIS) alongside demographic variables & the Mississippi Combat Scale (MCS; Keane, Caddell, & Taylor, 1988). The probability index ranged from 0 to 1 and was reported as a "strong estimate" of PTSD. In addition, 15 further items from the MCS were included as a measure of different clusters of symptomology; namely re-experiencing (five items), avoidance (five items) and hyperarousal (five items). The MCS is s self-report measure with items rated on a 5-point scale.

Beckham et al (1998) also used multiple measures, again utilising the MCS alongside the Clinician-administered PTSD Scale Diagnostic version (CAPS; Blake et al., 1995) and the Davidson Trauma Scale (DTS; Davidson et al., 1997) The DTS is a self-report scale measuring frequency and severity of PTSD as a total score as well as by symptom clusters (B, C and D scores). The CAPS is a structured interview also assessing PTSD frequency and severity and symptom clusters, including two guilt related items. The remaining seven studies used a single measure. Shea et al (2016) and Sippel and Marshall (2011) also opted for the CAPS, whilst Dennis et al (2017) also used the DTS. Stein et al (2012) utilised the PTSD Symptom Scale, Interview Version (PSS-I; Foa, Riggs, Dancu, & Rothbaum, 1993); a 17 item semi-structured interview which measures severity of PTSD relevant to a single trauma event.

The remaining four measures were the Revised Combat Scale (RCS; Egendorf, 1981), a checklist of PTSD symptoms based on the DSM-III diagnostic criteria & clinical interviews; the Structured Clinical Interview (SCID; Spitzer, Williams, Gibbon, & First, 1992) for DSM-III-R, the Detailed Assessment of Posttraumatic Stress (DAPS; Briere, 2001); and the PTSD Checklist (PCL; Weathers, Litz, Herman, Huska, & Keane, 1993).

Measures of Guilt

Two standardised measures of guilt were used; the Trauma Related Guilt Inventory (TRGI; Kubany et al., 1996) and the Laufer-Parson Guilt Inventory (LPGI; Laufer & Frey-Wouters, 1988). The TRGI is a 32-item self-report scale assessing cognitive and emotional aspects of guilt on a 5-point Likert scale. It comprises of a global guilt scale, a distress scale and a guilt cognitions scale (with three subscales: Hindsight-Bias/Responsibility, Wrongdoing, and Lack of Justification) and was the most commonly used measure being utilised in four of the nine studies investigating the role of guilt (Beckham et al., 1998; Crisford et al., 2008; Dennis et al., 2017; Stein et al., 2012). The LPGI was employed by two of the remaining five studies (Huang & Kashubeck-West, 2015; Marx et al., 2010); a 33 item self-report scale designed to measure combat-related guilt on a 5-point Likert scale.

In the remaining three studies measuring guilt, Currier et al (2014) used three 'yes' or 'no' questions as a means of measuring combat-related guilt; Shea et al (2016) utilised the two guilt-based questions of the CAPS; and Hendin and Haas (1991) used data coded from clinical interviews as representing feelings of guilt.

Jordan et al (2017) used a combined measure of guilt and shame by combining the scores for emotions identified as 'Ashamed' and 'Guilty' on the Positive and Negative Affect Schedule (PANAS; Watson, Clark, & Tellegen, 1988). The PANAS is a self-report measure traditionally used to measure positive and negative emotions on a 5-point scale, covering 20 different emotions when used in its original form.

Measures of Shame

Only one study measured shame as an independent variable. Sippel and Marshall (2011) developed an emotional stroop task which assessed participants processing speed to shame-based and neutral words. Words were presented electronically on a black background and participants were asked to name the colour of the word. Two forms of this task were developed; a supraliminal version where the word remained on the screen until a vocal response was given, and a subliminal version where the word was replaced by a mask of the same colour after a set time which then remained until a vocal response was given. In addition, participants also completed a self-referential encoding task whereby participants indicated whether shame-relevant words reflected their beliefs about themselves (i.e. their self-schemas).

Study Results

The Relationship between Guilt, Perpetration and PTSD

Eight of the nine studies investigating the association between guilt, degree of perpetration and PTSD severity evidenced significant relationships between the three factors.

Military Studies

Five studies (Beckham et al., 1998; Dennis et al., 2017; Huang & Kashubeck-West, 2015; Jordan et al., 2017; Marx et al., 2010) described a significant role for guilt in the relationship between involvement in acts of perpetration and PTSD severity. Of these five studies, four of them utilised means of measuring mediation through the use of Bootstrapping (Dennis et al., 2017; Huang & Kashuback-West, 2015), path analysis (Marx et al., 2010) and Structural Equation Modelling (SEM) (Jordan et al. 2017), providing analytical evidence of guilt as a mediating factor. Beckham et al (1998) did not provide a measure of mediation. Two studies (Currier et al., 2014; Stein et al., 2012) reported an inverse relationship between PTSD severity in the relationship between perpetration and guilt. Stein et al (2012) did not include a measure of mediation to demonstrate this suggestion, whilst Currier et al (2014) measured mediation utilising SEM. See appendices A – C for models of these relationships (plus any identified co-variates) presented by the authors in three of the nine studies (Currier et al., 2014; Dennis et al., 2017; Marx et al., 2010). Huang & Kashubeck-West (2015) found the mediation effect of guilt predicted variance above and beyond combat exposure and perceived threat.

Exploration of the symptoms of PTSD found significant effects of perpetration on symptoms of avoidance and numbing (Beckham et al., 1998) as well as re-experiencing (Stein et al., 2012) within models of guilt, perpetration and PTSD.

Marx et al (2010) found that guilt not only mediated the relationship between perpetration and PTSD, but had a significant indirect effect on MDD also; although, the magnitude of the variance was 2x that of MDD in PTSD. Dennis et al (2017) also found significant mediating effects of guilt on depression, hostility and aggression alongside within models of severity of PTSD and involvement in perpetration.

Shea et al (2016) did not replicate other studies, evidencing no significant relationships between any of the three key identified variables (PTSD, guilt and perpetration) for those classified in their sample as ’having killed’ (enemy or non-

combatants, n = 26) in combat. One possible reason for their contrasting non-significant result may be the use of actively serving soldiers as opposed to veterans. Active service members were also used in Stein et al's (2012) study which found a significant result in line with other studies included in this review.

However, whilst Stein et al (2012) shared a host of similarities with Shea et al (2016), including classifying their sample similarly according to trauma type and comparable sample sizes and populations, one noted difference in the samples is whether service personnel had been formally diagnosed with PTSD. In Shea et al's (2016) study, severity of PTSD symptoms was investigated in the absence of a formal diagnosis whilst participants in Stein et al (2012) were diagnosed with PTSD prior to participating in the study. It is possible that the differing level of PTSD severity may have accounted for the contrasting results. Another possible explanation for Shea et al's (2016) non-significance could also lie in their measure of guilt; they utilised two CAPS items from the PTSD scale as a measure of guilt as opposed to a standardised instrument.

Offender Studies

Crisford et al (2008) also evidenced a significant mediating role of guilt in predicting the relationship between degree of perpetration on PTSD severity alongside negative affect and offence severity. Mediation was reported via an increase in variance accounted for by the addition of guilt, which significantly increased the variance from 43% to 54%. A significant difference in guilt was also found between those offenders whose victims were known vs. unknown, with greater guilt in those who did not know their victim.

The Relationship between Shame, Perpetration and PTSD

Only two studies focused on the relationship between shame in perpetration-induced trauma and PTSD severity. In addition, only one of these two studies focused on shame as an independent variable (Sippel & Marshall, 2011), whilst the other (Jordan et al., 2017) discussed a combined variable of both guilt and shame.

Military studies

The military study compared the combined factor of guilt and shame (Jordan et al., 2017). It found marginally significant indirect effects of guilt and shame on PTSD in perpetration of harm. This was in contrast to similar relationships between anger as a mediator of acts of betrayal and dissociation as a mediator of danger-based combat

exposure. This distinction was suggested to evidence a particular role of guilt and shame in perpetration-based traumas as compared with other trauma types. See Appendix D for the reported model. Mediation was analysed via SEM.

Offender studies

Sippel and Marhsall (2011) reported a significant mediating effect of subliminal shame processing speed on an emotional stroop task in the relationship between IPV perpetration and PTSD severity. Bootstrapping techniques were used to analyse mediation.

The Role of Cognitive Variables in the Relationship between Guilt/Shame and Perpetration-induced PTSD

Military Studies

Exploration of different dimensions of guilt identified significant effects of perpetration on the role of hindsight/responsibility and a sense of wrongdoing but not lack of justification (as measured by the TRGI) on PTSD in military personnel (Beckham et al., 1998; Stein et al., 2012). Additionally, Beckham et al (1998) also found the same relationship with guilt cognitions on the TRGI; a similar finding to Stein et al (2012) who found an effect of perpetration on negative cognitions about the self in PTSD within a model of perpetration, guilt and PTSD.

Consideration of other co-variates also highlighted a significant difference across group comparisons in the degree of guilt felt about perpetrated actions in suicidal veterans with PTSD (both attempts and ideation groups) as compared to nonsuicidal veterans (Hendin & Haas, 1991) alongside a significant association between perpetration and peritraumatic feelings of being "out of control" in suicide attempters.

Offender Studies

Sippel and Marshall (2011) also found significant correlations between number of selected shame self-descriptive words and both PTSD severity, degree of perpetration of IPV and shame processing speed on the stroop tasks. They concluded that their results supported the role of a shame processing bias in the development of perpetration-induced PTSD in perpetrators of IPV. See Appendix E for the reported model.

Conclusion

This review has found some evidence to support the mediating role of guilt in the relationship between involvement in perpetration as a trauma and the severity of PTSD within the context of varying means of mediation analyses. Evidence from those studies which utilised statistical analyses of mediation such as Bootstrapping and SEM, all reported significant effects with all *p*s < 0.05. A similar relationship has also been demonstrated for shame; however, given that only one included study focused directly on shame, conclusions are unable to be drawn and further research on the mediating effect on shame are warranted.

Evidence for the mediating role of guilt in the relationship between perpetration and PTSD supports its role as a central mechanism in the development and/or maintenance of PTSD in those who experience the effects of a self-perpetrated trauma. This is supportive of Lee et al's (2001) model of guilt-based PTSD. The centrality of shame in Lee et al's shame-based model of PTSD was also supported; but significantly limited by the scarcity of evidence.

In considering the mechanisms involved in the relationship between guilt/shame and PTSD, Lee et al (2001) proposed a central role of cognitive appraisals and self-focused schema in the development of PTSD symptomology. Investigation of differing dimensions of guilt as measured by the TRGI identified a significant mediating role for a sense of responsibility and wrongdoing on PTSD severity (Beckham et al., 1998; Stein et al., 2012). This sense of disparity with an individual's personal (i.e. responsibility) sense of what they believe to be right and wrong (i.e. wrongdoing) is akin to Lee et al's (2001) identified incongruence between pre-existing schemas of the self and trauma appraisals. In addition, this relationship was found to exist in the absence of a lack of justification (as measured by the TRGI), emphasising the importance of the individual's meaning attributed to their actions (i.e. their cognitive appraisals of the perpetration trauma), regardless of how it is more widely viewed or justified by others. This finding is particularly pertinent in consideration of the role of perpetration-induced PTSD within the military and other occupations, whereby justification of actions by employers and occupation-related training should not be assumed to be protective of guilt-based or shame-based PTSD.

Cognitive appraisals were also supported as a mechanism in this review through the evidenced role of guilt cognitions (Beckham et al., 1998), negative thoughts about the

self (Stein et al., 2012) and shame schemas (Sippel & Marshall, 2011). Once again, this can be argued to be supportive of the central role of pre-existing schemas as well as the development of new negative beliefs in Lee et al's (2001) model. In addition, the finding is also supportive of the central role of cognitive factors in the NICE recommended cognitive behavioural therapy (CBT) treatment for PTSD (NICE, 2005). However, in light of some evidence noted during the full text screening for this review which suggested that some components of traditional PTSD interventions may cause more harm than benefit in shame-based PTSD (Maguen & Burkman, 2013). As such further research on the treatment of shame-based and guilt-based PTSD is warranted.

The role of both re-experiencing (Stein et al., 2012) and avoidance (Beckham et al., 1998) symptomology in guilt-based PTSD are also supported by the studies included in the review; both of these symptoms being highlighted in the models of shame-based and guilt-based PTSD (Lee et al., 2001) as well as the traditional cognitive model of PTSD (Ehlers & Clark, 2000).

It is noteworthy that significantly more studies focused on the role of guilt as compared to shame, perhaps due to a higher prevalence of guilt in PTSD as compared to shame, or alternatively presenting a bias in the literature. Comparative research on the differing prevalence rates of guilt and shame in PTSD could prove to be of interest in this regard, including figures on their co-occurrence. Furthermore, a distinction in this review also exists such that all military studies included in the review measured guilt, with the exception of one which reported a combined guilt and shame measure. Contrastingly, shame was only measured independently in the offender studies. This distinction in emotion focus is interesting, particularly given that both emotions have been evidenced to be predictors of PTSD (McLean & Foa, 2016) and related to moral transgressions (Tangney, 1996), and carry equal weight in relevant theoretical models (Lee et al., 2001).

Considering the definitions of guilt and shame within the context of the different acts of perpetration and the associated social and cultural perceptions, it seems fitting that lawfully sanctioned perpetrators (consciously or unconsciously) bring with them a focus on guilt ("I did a bad thing") whilst a focus on shame is present in perpetrators of *criminal* acts ("I am a bad person"). Future research would benefit from diversifying this focus such that the role of both emotions across both populations are investigated. This would also allow for a comparative exploration of the significance of each emotion in the two populations. One example would be to explore whether the non-significant result found in

the ‘Lack of Justification’ subscale in the TRGI (as opposed to other subscales) in military personnel would be a valid distinction in the offender population also given the unlawful nature of their act as compared to the sanctioned actions of a serving soldier.

In addition to providing early support for the mechanisms of the development and maintenance of PTSD highlighted by current theoretical models, the review also highlighted a number of additional areas for exploration in understanding further possible mediating factors in guilt-based and shame-based PTSD. For example, the role of hostility and aggression (Dennis et al., 2017) and a possible associated peri-traumatic feeling of being “out of control” (Hendin & Haas, 1991).

Finally, possible associated consequences of guilt in perpetration-induced PTSD were highlighted in military studies; namely, suicidality (Hendin & Haas, 1991); post-trauma emotions of ‘sad’ as well as depression and MDD (Dennis et al., 2017; Marx et al., 2010; Stein et al., 2012); and aggression and hostility (Dennis et al., 2017). Within the context of perpetration of harm being a hazard of their occupation, the importance of fully understanding the impact of this aspect of their role on mental health is key; particularly given recent figures from the US Department of Veteran Affairs estimating that in the USA (where all military studies in this review were conducted) one veteran dies by suicide every 80 minutes (Harrell & Berglass, 2011). Exploration of whether the mechanisms of such effects by guilt are specific to perpetration or whether this is part of a broader relationship between guilt, PTSD and these dependent variables would also be warranted. Furthermore, understanding these relationships in the context of offender populations would also be justified.

Limitations

The findings of the review need to be considered in the context of the methodological limitations of those studies included in the review. All studies included are cross-sectional in their design meaning that conclusions surrounding the role of causality and directionality in the relationship between variables cannot be drawn. This is particular pertinent when considering the results within the context of Lee et al’s (2001) model which offers a longitudinal perspective in suggesting a theoretical direction of this relationship (i.e. that shame or guilt schemas are either pre-existing and become activated by post-trauma appraisals, or subsequently develop as a result of peritraumatic appraisals of guilt or shame). Whilst this longitudinal element is difficult to investigate, consideration could be given to the development of experimental methodologies to explore the

possibility of a causal relationship between guilt and shame trauma appraisals and schema activation or development; for example, utilising guilt or shame based vignettes as a parallel.

In addition, sample sizes varied significantly across studies and those with smaller sample sizes may be underpowered meaning that whilst valuable contributions, the generalisability of their results are likely limited. Furthermore, three of the larger studies were based upon retrospective secondary data analysis; a method which has been criticised relevant to the validity of such studies (McNally, 2003).

None of the studies included a control group, meaning that comparison of the mechanisms in victims vs. perpetrators was not feasible. Inclusion of a comparative group would allow for firmer conclusions to be drawn surrounding the specificity of the mechanisms as linked to acts of perpetration as a trauma.

All military studies were conducted within the USA and given differing natures of armed forces across countries, the applicability of the results to the UK armed forces is limited. Other demographics of note was that the majority of participants in the studies were male. Given suggestions that a gender difference exists between the severity of PTSD, coping and trauma-related guilt in the armed forces (Hensley, unpublished), the generalisability of these findings is limited and additional research warranted in understanding any gender differences in the context of perpetration-induced PTSD.

Although some studies did use well validated instruments like the SCID or CAPS for PTSD, and the TRGI and LPGI for guilt, the reliability and validity of tools varied significantly across studies with some studies using a limited number of researcher-selected forced choice ‘yes’ or ‘no’ questions or interview data coded by the researchers; both of which are subject to experimenter bias. This limits the comparability of the results across studies and warrants further high-quality research utilising standardised measures with good levels of reliability and validity.

It is important to consider possible confounding variables. Whilst some studies explored the possible confounding role of degree of combat related exposure in the military studies, specific consideration of possible co-founding sources of trauma based upon a non-perpetration trauma was not considered. This is also important in the offending

populations, where it is known that offenders may likely also have a history of traumatic experiences as a 'victim' of trauma prior to the offence.

In addition to the methodological limitations of the studies included in this review, it is also important to consider the limitations of the literature review itself. Use of Google Scholar as part of the search procedure has its' limitations. These include the absence of controlled vocabulary and a whole text search strategy which can result in the retrieval of a number of inaccurate citations. However, on the contrary, Google Scholar's less precise search strategy has a broader reach, including covering multiple disciplines and multiple document types including gray literature (although excluded from this review due to accessibility constraints). Consideration of these advantages and disadvantages in relation to literature reviews has suggested that use of Google Scholar should be accompanied by other academic databases in order to ensure the best possible coverage of the literature using this search engine (Shultz, 2007). Furthermore, within the context of a systematic review, it is also worthy to note that the algorithm of Google Scholar is changed regularly which impacts significantly on the ability to replicate the search accurately.

Furthermore, whilst the methodological quality of the studies included in the review is critically discussed throughout, inclusion of a quality assessment tool would have provided an objective measure of the quality of the studies included. This would allow for firmer conclusions to be drawn in relation to the quality of the literature in the field.

Clinical Implications

Clinical implications of this review include the importance of therapists' consideration of the potential role of guilt and/or shame in the development of PTSD. This is particularly significant given evidence indicative of a lack of effectiveness of traditional interventions for PTSD such as CBT (Steenkamp, Nash, Lebowitz, & Litz, 2013) with suggestions that the exposure components of such treatments may in fact exacerbate shame-based reactions to transgressive events (Maguen & Burkman, 2013). As such, evaluation of the current NICE recommended means of treating PTSD as well as consideration of alternative interventions would be warranted in further research in this field. For example, one study considered at the full text level of this review highlighted the importance of addressing compassion for the traumatised self when working with shame-based PTSD in military personnel (Alliger-Horn, Zimmermann, & Schmucker, 2016).

Consideration of therapist views may also be warranted given the controversial nature of working with a traumatised perpetrator.

In addition, throughout the screening process of this review, what became apparent is the increasing recognition of the role of perpetration-induced PTSD beyond the military into other occupations including slaughterhouse workers, veterinarians, medical professionals (including 'medical error' in the case of surgeons, medical consultants, paramedics and midwives) and police (Dillard, 2008; Komarovskaya et al., 2011; R. MacNair, 2002; Victor & Barnard, 2016; Wahlberg et al., 2016; Whiting & Marion, 2011). In comparison to the military population, research into the role of PTSD in other professions remains minimal. This may be reflective of a much-reduced prevalence rate in these populations as compared with the military. Nevertheless, killing or seriously injuring another in a professional role remains a significant predictor of PTSD for other populations also (for example, police officers; Komarovskaya et al., 2011). This highlights the importance of further research considering the wider reach of perpetration-related PTSD in the context of one's occupation. With the literature surrounding the relationship between these professions and PTSD being scarce, exploration of the mechanisms of this relationship is absent meaning that no additional professions were included in this review. Further research would be beneficial.

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University of Bath
Doctorate in Clinical Psychology

Service Improvement Project

Evaluating Service Need for a Patient Decision Aid Tool (PtDA) for Patients Considering Lung Transplantation in an NHS Cystic Fibrosis Service: An Assessment of Patients' and Clinicians' Perspectives

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Date: June 2017

Word Count: 4,982

Proposed Journal for Publication: Journal of Cystic Fibrosis

Introduction

Lung transplantation in Cystic Fibrosis

There are currently over 10,000 people living with Cystic Fibrosis (CF) in the UK (Cystic Fibrosis Trust, 2015). CF is a hereditary disease which causes excessive mucus secretions, primarily affecting the pancreas and lungs and causing significant pulmonary damage. As medical knowledge and treatment develops, survival rates have improved significantly with the recent predicted age of survival being greater than 50 years (Dodge, Lewis, Stanton, & Wilsher, 2007). Consequently, CF is no longer considered a childhood disease and focus on long-term management has increased (Goldbeck, Fidika, Herle, & Quittner, 2014).

Lung transplantation has become an established treatment option for many patients with advanced disease (Mall, 2014) and the Cystic Fibrosis Trust has consequently called for improved access to transplantation (Cystic Fibrosis Trust, 2014). Nevertheless, it does not come without difficulties and significant complications post-transplant are common (Cystic Fibrosis Trust, 2013). Current figures suggest that in the UK, NHS transplants see an average survival rate of approximately 8.1 years, although this figure varies significantly (Cystic Fibrosis Trust, 2015). Unsurprisingly, the decision to go ahead with lung transplantation is complex and difficult.

Patient Decision Aid Tools

One suggestion of how services can better support patients and their families with complex decision-making is through the use of patient decision aid tools (PtDAs) (O'Connor et al., 2009). Coulter (2013) outlined the overarching goals of PtDAs as addressing inadequate knowledge and unrealistic expectations, reducing unwanted pressure and improving support. Use of these tools has also been suggested to support shared decision making; a concept at the centre of many UK healthcare policies (Lansley, 2010).

Over 80 RCTs support the efficacy of PtDAs in supporting complex decision making in chronic physical health problems (O'Connor et al., 2009), including one utilising a PtDA in lung transplantation in CF (Vandemheen et al., 2009). Vandemheen et al (2009) demonstrated the PtDA to be a beneficial adjunct to care as usual in reducing decisional conflict, increasing patient knowledge and understanding of the procedure, process and associated risks, facilitating more realistic expectations and improving patient satisfaction with the decision-making process.

However, despite substantial support from RCTs, implementing PtDAs in routine practice is not without challenges. Elwyn et al (2013) outlined the need for services to understand how to best use such tools. In line with this, O'Connor (1998) highlights the importance of considering clinical characteristics such as patient and provider perceptions of decisional support at the earliest stage of PtDA development. Current research surrounding the utilisation of a PtDA for lung transplantation in CF exists within the Australian and Canadian healthcare systems only. It has not yet been replicated within a UK NHS-based service. Without sufficient consideration of the service context, services are suggested to be at risk of causing harm as opposed to improving care (Coulter et al., 2013).

The Service: Bristol Adult Cystic Fibrosis Centre

Bristol Adult Cystic Fibrosis Centre is a specialist centre providing multidisciplinary care to adults with CF across the South West. The team comprises two consultant physicians, 5 CF nurses, 4 physiotherapists, 2 dieticians, 2 clinical psychologists, 2 pharmacists and a social worker. The service is directly attached to the Bristol Paediatric CF service, although also accepts referrals from other paediatric services.

Aims of the Study

The purpose of this study was to explore whether introducing a PtDA into a UK NHS-based service could improve patient care for adults with CF considering lung transplantation. At this early stage of development, the clinical needs of the service, patients and carers were evaluated. A qualitative approach was taken to reflect the exploratory nature of the research. A full evaluation of clinician, patient and carer views about current levels of support within the CF service was completed alongside exploring whether a PtDA for lung transplantation could improve care provision. Vandemheen's et al (2009) PtDA was offered as an example to support consideration of how such a tool might best be implemented.

Methodology

Design

Following consultation with the Clinical Lead and Clinical Psychologist, research questions were outlined as follows:

1. Is current service provision for lung transplantation meeting patients' needs?
2. Would the introduction of a PtDA improve service provision?
3. What would the potential benefits of introducing a PtDA be?
4. What would the challenges of introducing a PtDA be?
5. What adjustments would need to be made to ensure the PtDA was meaningful to the service?
6. If a PtDA was introduced, how should it be delivered?

These questions formed the basis of the focus group and interviews and were asked after provision of a brief outline of the aims of a PtDA and research to date (via PowerPoint presentation to clinicians (Appendix G) and verbally to patients and family). All participants were provided with a copy of the PtDA (Vandenheem et al., 2009) (Appendix H). Questions were delivered flexibly with prompts whilst remaining sufficiently open to allow important aspects to be identified by participants.

Participants

Data saturation (Glaser & Strauss, 2009) is the guiding principle by which sample size in qualitative research should be determined. When data saturation is achieved, content validity can be concluded (Francis et al., 2010). In the current study, recruitment of patients and family members was necessarily limited by the inclusion criteria set by the service; due to the sensitive nature of the topic, participants had to have undergone lung transplantation, be on the waiting list for one, or were a family member of a patient in either position. This limited pure data saturation but analysis demonstrated significant overlap in data coding and emerging themes, demonstrating adequate content validity.

All clinicians currently working in the service were invited to take part with the aim of capturing a multidisciplinary perspective. Participants were 10 clinicians (C1 – C10); a Consultant Physician, Registrar, Dietician, Nurses, Clinical Psychologists and Physiotherapists. 3 patients (P1 – P3) and 2 family members (F1 – F2) took part in the interviews (see Table 2.1 for demographics). All participants were White British.

Participant number	*Age*	*Gender*	*Patient/Significant Other*	*Lung transplantation status*
P1	20s	F	Patient	Awaiting lung transplantation
F1	50s	F	Carer	Parent of P1
P2	20s	F	Patient	Undergone lung transplantation
F2	40s	F	Carer	Parent of P2
P3	50s	F	Patient	Awaiting lung transplantation

Table 2.1: Demographic information for patients and family members

Procedure

Invitations to attend the focus group were sent to clinicians via secure email. The focus group took place during time allocated for a team meeting at the Bristol Adult CF Centre. The focus group and interviews lasted between 45mins – 1hour, were audio-recorded, transcribed verbatim and anonymised.

Potential patients were approached by known clinicians from the service; six were identified, however three were not included as one had a significant health event, one died and the other declined inclusion. The remaining three were provided with an information sheet and contacted by the lead researcher within 7 days to arrange a convenient time to meet. The researcher then asked the patient if they could identify a family member who would be interested in participating also. Two patients invited a parent to attend and one patient declined. The interview with the individual patient also took place at the Bristol Adult CF Centre during a routine hospital admission. The two patient/family interviews took place in their place of residence.

Analysis

Analysis and transcription were conducted as parallel processes. The lead researcher conducted the interviews, transcribed and analysed the data. Analysis followed the six-phase guide to thematic analysis outlined by Braun & Clark (2006) with initial coding completed inductively and the service's research questions acting as a deductive framework for later stages of analysis. This is in line with the Thematic Framework Method (Gale, Heath, Cameron, Rashid, & Redwood, 2013; Ritchie, Lewis, Nicholls, & Ormston, 2013)

After transcription, the researcher read each transcript several times, to promote data familiarity, and search for patterns of meaning. Initial codes were noted onto the transcripts and linked to relevant extracts. Coding began using an inductive process, as this allowed for the richness of the original data to be captured. These initial codes were then grouped together using a deductive approach, guided by the research questions, and linking together codes that had shared similarities in meaning to generate meaningful and valid 'themes'

In an attempt to capture the full richness of a theme, conflicting codes were included together for consideration. Transcripts were re-read frequently throughout this process. Within each identified theme, codes were organised into subthemes to more closely capture the essence of the original transcripts.

Once initial analysis was complete, a second rater analysed a sub-set of the data. The second rater, a Clinical Psychologist in training with experience of working within the Bristol adult CF service, offered an informed and alternative perspective on the data. The second rater first reviewed the coding of one theme in detail and then reviewed the remaining themes and subthemes based on a subset of codes within each. They were then consulted on the proposal to merge two themes that had initially been distinct. Their analysis fed into the final analysis and review of the themes. Examples included retaining the merged theme due to inter-rater agreement, merging subthemes due to identified overlap and assistance in defining subthemes which led to a high level of inter-rater agreement on the remaining themes when discussed.

Statement of position

The researcher positioned themselves within a phenomenological framework as a means of attempting to capture the experiences of the participants taking part in the study. Within this framework, they considered themselves to be approaching the data from an experiential viewpoint, whilst also recognising a constructionist influence given the role of the service's research questions as a deductive framework in analysis. The researcher is a Clinical Psychologist in training who does not have any experience of working with adults with Cystic Fibrosis. A deliberate decision was made to limit the researcher's knowledge of the lung transplant process so as to not to create any biases on the participants' views on the decision-making process.

Ethics

The study was assessed and approved by The University of Bath Psychology Department Research Ethics Committee. Full NHS ethics was not required as the study met criteria for service evaluation. All participants were provided with information sheets and gave consent to participate in the knowledge that their data would be anonymised and that they could withdraw at any time.

Results

A significant overlap was found in themes arising from data provided by staff, patients and carers, so all themes are reported together. Six super-ordinate themes were extracted from the data: 1) 'Meeting needs'; 2) 'Accessibility''; 3) 'Choice''; 4) 'Communication'; 5) 'Being prepared'; 6) 'Developing the tool' (see Appendix I for thematic map). These super-ordinate themes and their sub-themes are outlined below, illustrated by specific quotations.

1. *Meeting patient needs*

Patients reported variability in how well the service met their needs when deciding whether to proceed with lung transplant. They suggested that the PtDA may have a role in enhancing support.

1.1 The need for information

Patients and their families suggested that informational support needs were scarcely met by current service provision. Specifically, knowledge of the transplant process, potential advantages and disadvantages, transplant aftercare and possible outcomes post-transplant:

"*…well we just didn't have any information…we didn't know how it worked or what it entailed… it would have been beneficial to know*" (P1).

One patient interpreted this lack of information as the service not having the knowledge to disseminate to patients:

"*…to be honest, they don't know a great deal I don't think. They just sort of say about it and then the rest is up to you to…find out really…I don't think they want to give the information because they don't know*." (P1).

This lack of knowledge led some patients to do their own (online) research, and the potential dangers of doing this were acknowledged by patients and staff. Clinicians suggested that addressing this gap through the PtDA would ensure that accurate information is received:

"*patients who are anxious are probably surfing the net anyway and at least we have got some control over what is in the content of this*" (C4)

Another patient spoke of the absence of information acting as a barrier to asking questions:

"*…it is also a question of me having the knowledge to ask them what might happen and I don't think I have that knowledge…I don't know what to ask..."* (P3)

Patients and family felt that the PtDA could address the identified gaps, and thus make decisions more informed:

"*…I think this would have definitely made the decision process…more knowledgeable…everything is there… how your life can be with the transplant but there is also without the transplant…you have everything you need before you to make that decision…I personally think it is brilliant and would've been really helpful to have*." (F2).

1.2 Emotional support

The need for emotional support was emphasised by patients and family, all describing positive experiences of emotional support by the team:

"*the team themselves are really supportive*" (P1)
"*…the support I have received has been very good*…" (P3)

One patient identified difficulties forming new relationships and building trust after her transition from paediatric to adult services as a barrier to accessing emotional support during the decision-making process. She suggested a more informal approach to meeting patients:

"*…just a more friendly and understanding level rather than…being a bit more professional about it because that's when I put my guard up because I just thought they were telling me things…"* (P2)

The PtDA was suggested as having an emotionally supportive role in addition to improving knowledge:

"*I think it is pretty much on point…feeling supported through it, to have this…*" (F2).

1.3 Supporting physical health

One patient suggested that support focused too much on physical health preparations for transplant and that non-physical needs should be met too:

"*… it was more about the physical stuff and it was all about my weight…there was good communication for physical stuff too but the other support, it felt like it didn't kick in soon enough..."* (P2)

1.4 Tool as an adjunct

The role of the PtDA was regarded by both patients and staff as being best placed as an adjunct to the existing service:

"…you'd have the information…but also if you're giving it to them in clinic you can talk through the numbers at that point…It's not something you just send off in the post and say see you later. You know it's something that you would then have a discussion with them…" (C3)

Risks of giving the PtDA-based information alone were suggested by both staff and family as having the potential to overwhelm some individuals due to the difficult emotions that can be involved in making the decision:

"*I think one of the things that slightly concerns me is whether people um kind of naively go and look at the decision aid and think they'll be able to cope with it and then come overwrought."* (C4)

One clinician thought the front-sheet of the PtDA should inform patients that they can discuss the information with their team:

"I *mean that's something that you could put on the front-sheet, couldn't you? In terms of saying that it's for you and then the other ways are to talk to your team, psychology support, and all that kind of thing…"* (C2)

In order to reflect the team approach, both staff and patients felt that the PtDA could be introduced and reviewed by any member of the multidisciplinary team:

"I think it could be used by everyone because you know, they're a team, you need it from everyone…" (P2)

2. *Accessibility*

Equal access to the PtDA and the information it provides was suggested to be an important factor in considering its' use within the service.

2.1 Information being available

Clinicians and patients felt that the PtDA should be widely accessible, at all time points along the care pathway and that patients should be able to choose when to access the PtDA:

"if they wanted to know about it and felt ready for it then yeah I don't see the problem" (P2)

However, one patient spoke of the importance of not giving information at a time when it may be too anxiety-provoking, suggesting a need for the team to balance patient choice with clinical judgement when introducing the PtDA:

"*…if you're not at that stage…it might worry them even more and they may not need to be thinking about it*" (P2)

All participant groups mentioned the benefits of widening access to include family members as well as patients. As lung transplantation decisions are not made alone, having informational support via the PtDA would benefit families too:

"*oh yeah make it widely available to families so anybody can access that information. Yes, it is ultimately the patient goes through the process but we need to know that too, we need to know what they are going through*" (F2).

2.2 Information being understandable

Accessibility of information in the PtDA requires clarity and comprehensibility as well as physical access. One parent praised the simplicity of the language used in aiding her ability to understand otherwise complex medical information:

"*…it is simple, it doesn't use medical terms for anything that you don't piggin' understand, it's just so simple…*" (F2)

Supporting the written information with pictures and graphs was also suggested to be helpful in ensuring that the message is clear:

"*I think that it's really helpful having the pictoral form as well*" (C5)

3. *Choice*

Promoting and respecting patient choice when introducing the PtDA was seen as crucial by both clinicians and patients, given the complexity of the decision-making process.

3.1 Choosing how and when to use the tool

In considering the 'readiness' of patients to receive and process the information presented by the PtDA, patients and family suggested the right time as being a choice they make:

"…I think I pigeonholed this, I'm not gonna worry about that now… I knew it was there but kind of I don't need to deal with that at this moment thank you." (F2)

Clinicians suggested the PtDA could act as a means by which patients can make this choice:

"*they can read at a time when they're not too stressed about it. I think that's really important because it could be hard to process all that information at a time when you are trying to make that decision…*" (C5)

Clinicians and patients thought that having a choice of modality of the PtDA (online or on paper) would help:

"(having paper and online copies) *gives the patient choice so it feels much less paternalistic than what medicine could be like, it sort of gives the information when it is useful and needed*" (C4).

"*…because some people might…prefer it on email or online so they can get hold of it when they want to…whereas when it is on paper, it's like it's there…also online you have to be interested in looking for it and reading it whereas on paper it's here all the time and you can put it to one side…*" (P2).

Clinicians also highlighted the relationship between choice, engagement, and having options:

"*…you could make it (*a quiz) *an optional thing and say something like if you wanted to check that you have taken this in…but yeah I wouldn't make it a sort of mandatory part of the decision aid*" (C5)

3.2 Choice to make and change the decision

All patients discussed how their decision changed multiple times and highlighted the importance of feeling in control. Two patients said they had felt supported by the team to make their own choice:

"*The support I've had has been very good and nobody had pushed me into making that decision, it has been entirely mine*." (P3)

One patient and her mother spoke of a need to ensure clinical judgement doesn't overshadow patient choice:

"*...before I felt like people were saying I have to do it…and I sort of rebelled…*" (P2)
"*...this is helping you make a decision from that very start, we didn't have that decision, we were just referred*." (F2)

Clinicians outlined the importance of supporting patients with changing decisions:

"...saying that you've got time to make that decision and you have the choice of changing that because I think a lot of people worry that once they've said one thing then you can't go back and change it so I think that having that clear throughout..." (C6)

Both clinicians and patients spoke of the neutrality of the PtDA as being in keeping with the promotion of patient choice:

"*...it's quite benign, it's not really edited, not really pushing one way or the other*." (C1)

However, concerns were raised by groups about timing; highlighting the tensions between promoting patient choice within the context of a declining health condition:

"*...that decision can change but they have to be aware that actually it it's left too late then you might not have a choice about it*" (C3).

4. *Communication*

Another benefit of the PtDA was using it as a communication tool between staff, patients, family, and services.

4.1 Communication across services

Communication between services was an area that could be improved:

"*...there should be more communication…. I don't actually know whether one team communicated with the other…"* (F2)

The potential of using the PtDA as a consistent tool that patients bring to appointments with services at transition points was highlighted, specifically from the CF team to the transplant centre and from paediatric to adult services. In addition, it was suggested to enhance direct communication between services about patient readiness for transplant. This was considered to be a way of reducing anxiety when speaking to other professionals:

"*...so if you've got something that is already familiar to you that makes them a bit more relaxed, doesn't it?"* (F1)

4.2 Starting conversations

The PtDA was seen as a way of starting conversations with patients that the team may have not otherwise instigated, perhaps if their clinical judgement made them unsure about patient readiness. Consequently, the PtDA could help with reaching out to more patients and families:

"*I think for me where this feels like it's helpful is for the people who we don't even know are thinking about transplant*" (C1)

5. *Feeling prepared*

All patients and family members described how the conversation about lung transplant came as a shock, for which they felt unprepared:

"*I had like never heard about it being done before in like CF, it's sort of shocked me because I didn't know that like that was an option*" (P1)

The PtDA could improve care by preparing patients for this discussion.

5.1 Drip-feeding information

One patient spoke of the benefits of having information about lung transplant in the PtDA early on in their care:

"*…drip feeding it slowly so it isn't a shock*" (P1)

5.2 Seeing change over time

Patients and staff suggested that routine use of the tool in clinic make all parties aware of health changes over time, potentially ameliorating the shock of being told they are unwell enough to have a lung transplant:

"*…maybe if you see it gradually coming like this in this sort of form you would gradually become aware or accepting of eventually these things are gonna happen and it won't be, not such a shock but you'd perhaps be able to cope with it a bit better yeah*" (F1)

This use of the PtDA could give patients and families a more realistic picture of their health and treatment options:

"*…it was a shock in a way because I thought am I really ill enough for a lung transplant? This would of brought me back to reality…*" (P3)

The 'tick boxes' were suggested as particularly useful in tracking change over time:

"*I think it might be beneficial to use the tick boxes like to go through it every so often*" (P1)

6. *Developing the tool*

All participants spoke positively about the supportive nature of the example PtDA. Various developments and adaptations were suggested to improve the tool and ensure it could be used meaningfully within the service.

6.1 Making service specific developments

The need to adapt the Australian version of the PtDA to reflect the UK National Healthcare System and UK facts and figures for CF was highlighted. The content was seen to need amendments so that it fitted with the service and was more meaningful for patients:

"*…it's something to develop so the tool is specific to us*" (C3)

One team member emphasised the need to evaluate the PtDA after any developments and subsequent introduction into the service:

"*if we developed it, how would we, would we try to evaluate? How would we plan to evaluate its use?*" (C3).

6.2 Future development

The team described possibilities for further expansion of the PtDA to continue to improve their service. For example, by developing a child-friendly PtDA:

"*…in some ways it might be something that's got potential, it would be nice to have like a younger version, a child-friendly version for parents to go through with their children…we've had requests already, you know, how do I explain this to my child?"* (C4)

This would improve conversations between the team and the children of parents with CF. This linked to the theme of 'Communication' between paediatric and adult CF services, and improvements in the transition process.

One patient and her mother also suggested including the patient voice in the tool, sharing valuable lived-experience of someone who had already undergone lung transplant:

"*…maybe giving a little bit of help from someone who has had a transplant who has been there trying to make the decision"* (P2).

Discussion

Evaluation of current service provision suggested that although patients and their families feel supported in managing the emotional impact of the lung transplant decision-making process, significant gaps exist in the availability of information. This suggests that the Bristol adult CF service could benefit from developing their informational support, with a particular emphasis on balancing the different types of support available to their service users.

The PtDA was seen to offer multiple benefits for service provision. An important part of this was as a way of improving informational support, but other aspects were also important, including enhancement of emotional support and communication. The strongest themes to arise around the benefits of the PtDA focused on how it could: improve access to clear and accurate information for *all* patients and their families; provide a neutral means of weighing up a complex decision without influence; and encourage regular, routine conversations between clinicians and patients. These benefits are closely aligned to the overarching goals of PtDA's (Coulter, 2013) of addressing inadequate knowledge and unrealistic expectations, reducing unwanted pressure and improving support. The data also support the role of a PtDA in improving shared decision making through the promotion of shared monitoring of health status and treatment options (Lansley, 2010).

However, introducing a new tool is has challenges and potential concerns about developing a PtDA in the Bristol adult CF were highlighted. The team should be able to respond to these concerns so patients are not put at risk (Coulter et al., 2013). This requires the balancing of clinical responsibility and duty of care with patient choice and information provision in a way that is supportive and not overwhelming. One such tension that the team will need to consider carefully when developing the tool further, is ensuring

patients and families are fully aware of the limits of the decision (i.e. when other factors will deem them unable to have a transplant) without influencing their choice.

The need to adapt and tailor an example PtDA to the specific service (and the UK healthcare system more generally) was seen as important, demonstrating how critical it is to explore and use input from services, clinicians and patients at the early stage of PtDA development (Elwyn et al., 2013; O'connor et al., 1998). Similarly, it is not sufficient for benefits to be assumed, and any tool development must be properly evaluated to ensure it meets patient and service requirements.

Overall, this study demonstrated staff, patients and families' enthusiasm for the PtDA and its acceptability. To build on this further, research should now be conducted in the development, implementation and evaluation of a PtDA within the service. If such evaluation studies suggest it leads to measureable benefits, then a larger RCT could be explored (e.g. Vandemheen et al., 2009). It could also be of interest to explore the use of a PtDA within paediatric services too.

Limitations

This study aimed to explore the use of a PtDA in a single service for adults so data were gathered from a small sample. Consequently, conclusions regarding the acceptability of a PtDA in CF services in the UK more generally cannot be drawn. In addition, given the sensitive nature of this topic, patients included were either on the transplant list or had undergone transplant. Given suggestions that earlier introduction of information would be beneficial, consideration of the views of patients for whom lung transplant has not yet been discussed would be warranted.

Recommendations for the service

From the resulting themes, a number of recommendations for the Bristol adult CF service were made as outlined in Table 2.2. The lead researcher presented these recommendations at a subsequent team meeting and discussed ways in which the resulting recommendations could be implemented. The recommendations were also circulated to the team via secure email after the meeting. Given the beneficial role that the PtDA could have in improving service provision, the team are keen to begin to take steps to develop a service-specific tool to be introduced, based on the findings and recommendations of this study.

Area	Suggestions
PtDA content	**1.** Facts, figures and information included in the tool need to be adapted from the Australian example to accurately represent a UK context **2.** Important factors to be considered in developing the content include the accuracy of the information presented, including the source from which it is obtained, and the clarity with which it is presented **3.** Avoid medical language and ensure that the information is simple and factual in nature **4.** Clearly state on the front of the PtDA that the information contained within the PtDA can be discussed with their CF team **5.** Emphasise within the PtDA that the decision is theirs and that this can change **6.** Make clear the limits of the decision; for example, when that choice to have a transplant may no longer be viable
PtDA formatting	**1.** Include pictures and graphs as a means of supporting the written information content **2.** Both a paper and online copy should be made available to allow patients a choice of how and when they access the information **3.** Quiz section of the PtDA should be made optional **4.** Include the tick box summary sheet as a snapshot of where the person's health is currently in their consideration of whether this may be an option
Introducing the PtDA	**1.** The PtDA should be an adjunct to usual clinical care from the team and as such its introduction may be best placed alongside discussion from a team member **2.** The PtDA can be introduced by any member of the team 3. The introduction of the PtDA should be a routine part of care for all patients **4.** Patient choice in how and when they choose to access and engage with the Information should be respected. Related to this, all patients should be given both a paper copy as well as a link to the online version so they have choice in how they wish to access the tool **5.** Introduce the tool not only to patients themselves but also ensure significant others, including family, are aware of the PtDA and its use and are able to access it if they feel it would be helpful **6.** Introducing the tool earlier in the care pathway has been suggested as a means of increasing preparation for the decision-making process through gradual awareness and acceptance of the information presented. Gaining views of patients earlier on in the pathway would be beneficial in considering this further **7.** Whilst promoting patient choice is key to its implementation, a role for clinical judgement has also been suggested to be beneficial in ensuring that individuals do not become overwhelmed by the information without the necessary support in place

Ongoing use of the PtDA across the care pathway	**1.** Regularly use the PtDA at clinic appointments as a means of making the information a routine part of patient care **2.** Routinely complete the tick box summary sheet as a means of tracking change over time and enabling all parties to see when and why lung transplant should be considered as a viable treatment option if and when the time comes **3.** Explore the possibility of utilising this tool as a means of communicating with other services (e.g. transplant centres and paediatric services) to aid transitions for patients
Ensuring it is meeting the outlined needs	**1.** Once the tool has been developed, evaluation of its use in the service would be warranted
Further developments	**1.** Consideration of developing a child-friendly version of the PtDA in the future should initial introduction be evaluated positively **2.** Consider developing the tool further to include descriptions of the experience of making the decision from the perspectives of patients and family members alongside the factual information provided. Given the praise surrounding the neutrality of the document, whether these are incorporated into the PtDA or a separate document/leaflet is developed should be discussed and carefully considered

Table 2.2: Recommendations for developing and implementing a PtDA into the Bristol adult CF service

Conclusion

The findings demonstrate that current service provision for lung-transplant is broadly acceptable in this UK NHS-based adult CF service. However, there are some areas where improvements could be made, particularly around information provision, communication and accessibility. A PtDA tool could support such developments effectively, and patients, family and staff saw a wide range of benefits that could occur alongside the introduction of such a tool. Future development requires that a service-specific PtDA is created with the aim of improving access to information that will enhance informed decision making, emotional support and promote greater involvement of patients and families in treatment decisions. If such is carefully developed, implemented and evaluated, there is a clear pathway to improved clinical practice and patient care.

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University of Bath
Doctorate in Clinical Psychology

Main Research Project

The Role of Health Anxiety in Mild Cognitive Impairment

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Date: June 2017

Word Count: 5,295

Proposed Journal for Publication: British Journal of Clinical Psychology

Introduction

Mild Cognitive Impairment (MCI) is a diagnosis which describes the 'gap' between healthy ageing and the early stages of pathological cognitive decline (Yates, Clare, & Woods, 2013); that is, people who appear, on the basis of their cognitive functioning, to be showing 'milder' signs of the type of cognitive decline often seen in dementia, in some instances as a prodrome.

Peterson et al's (1999) original diagnostic criteria outlines MCI as follows: 1) subjective reports of cognitive decline; 2) evidence of objective cognitive impairments on neuropsychological testing; 3) cognitive complaints beyond what is expected for age; 4) otherwise intact activities of daily living (ADLs). However, as it stands, there is no universally agreed classification system, with around 16 in existence, each one varying in the degree to which they place emphasis on different criterion (Stephan, Brayne, McKeith, Bond, & Matthews, 2008). Divisions also exist relevant to the primary complaint (amnestic vs. non-amnestic) and the number of cognitive domains affected (single vs. multiple) (Yates et al., 2013), emphasising further the heterogeneity that this label holds.

Whilst a proportion of individuals with MCI progress to a dementia, this is not universally the case with some experiencing stability of impairment or even improvements (Bowen et al., 1997; Kluger, Ferris, Golomb, Mittelman, & Reisberg, 1999). The number of individuals who develop dementia also varies significantly, with prevalence rates ranging from 6.6% - 35% (Artero et al., 2008; Wahlund, Pihlstrand, & Jönhagen, 2003), demonstrating that heterogeneity exists not only in diagnosis but also in outcomes according to context and sampling.

With MCI becoming one of the most commonly delivered diagnoses in memory services (Wahlund et al., 2003), this heterogeneity is not without controversy and a number of ethical dilemmas have been highlighted. These include how best to explain this label without causing unnecessary distress, as well as avoiding stigmatisation (McKinlay, Leathem, & Merrick, 2014; Werner & Korczyn, 2008).

These ethical dilemmas are also central to the experience of individuals with MCI. Beard and Neary's (2013) grounded theory approach found overarching themes of uncertainty relevant to the definition of MCI as well as the distinction between MCI as normal ageing vs. a dementia prodrome. They suggested that such ambiguity creates social and psychological tensions and that the fear of negative consequences associated with

dementia can cause a 'courtesy stigma'. Government policies promoting earlier diagnosis have consequently been suggested to be at the detriment of emotional well-being (Gomersall et al., 2015; Le Couteur, 2013). What is more, with minimal to no evidence for the efficacy of interventions (Chandler, Parks, Marsiske, Rotblatt, & Smith, 2016; Cooper, Li, Lyketsos, & Livingston, 2013; Stott & Spector, 2011), the diagnosis is too often given with little or no support.

Investigation of illness representations have found marked bimodal distributions on the consequences (i.e. effects of MCI) and coherence (i.e. understanding what MCI is) subscales of the IPQ-MCI (Lin, Gleason, & Heidrich, 2012). In addition, the three most frequently endorsed (≥ 50%) attributed causes of MCI were ageing, hereditary/genetic risk factor and abnormal changes in the brain. This study proposes that the discrepancy in attributions, understanding and predicted consequences of MCI, occurring within a context of uncertainty and ambiguity, warrants consideration of a possible role of Health Anxiety (HA).

Increased levels of HA has been shown to be associated with a negative response to ambiguous health information (Rimes & Salkovskis, 2002) and neurological disease (Multiple Sclerosis; (Hayter, Salkovskis, Silber, & Morris, 2016) & Parkinson's Disease; (Fixter, 2015). Salkovskis and Warwick's cognitive model of HA (1986) proposes that attribution of health-related information to serious physical illness, produces and maintains a sense of current threat to health. The belief that one is developing a dementia has been suggested to produce an ongoing health threat in individuals with MCI (Suhr & Kinkela, 2007b). Furthermore, this belief has also been found to be associated with perceived negative consequences of MCI (Galvin, Fu, Nguyen, Glasheen, & Scharff, 2008).

A sense of threat has also been found to influence help seeking behaviours in MCI (Galvin et al., 2008), another parallel to Salkovskis and Warwick's HA model. Avoidance of health professionals and/or friends/relatives with memory concerns, thought suppression, hypervigilant "symptom checking" and higher levels of treatment seeking behaviour have all been evidenced in individuals with MCI (Corner & Bond, 2004; Hodgson & Cutler, 2003; Suhr & Kinkela, 2007a); all of which are in line with the proposed role of safety seeking behaviours (Salkovskis, 1991) in HA.

The role of HA in differing reactions to a diagnosis has been demonstrated within the context of long term physical health conditions, including patients with Relapse and

Remitting Multiple Sclerosis (RRMS) and Parkinson's Disease (Fixter, 2015; Hayter et al., 2016). In both studies, a high HA group reported poorer quality of life (QoL) as compared to a low HA group and healthy controls, independent of level of disability. They also found that those with high HA were more likely to subjectively rate their performance on tests of cognitive function as poorer and attribute their performance on these tasks to their health condition, independent of objective performance. In spite of suggested associations between MCI and poor subjective ratings of cognitive performance (Werner, 2003), health related worries (Wisocki, 1988) and QoL (Bárrios et al., 2013), the nature of these relationships are yet to be investigated.

Consequently, this study aims to investigate the proposed relationship between HA and individuals' experiences of MCI. Specifically, it is hypothesised that perceived QoL, subjective ratings of cognitive performance and attribution of cognitive performance to MCI will all be adversely impacted by high levels of HA, independent of level of objective impairment. In addition, the study also investigates the relationship between HA and illness representations in MCI; specifically, the consequences and causes domains of the IPQ-MCI.

Methodology

Participants

Two groups of participants were recruited: a group of older adults with a diagnosis of MCI (n = 45) and a normative sample of healthy controls without cognitive impairments (n = 17). Participant incentives were not provided.

Potential participants for the MCI sample were identified by clinicians working in four NHS Memory Services across the South West regions. They were approached by the identifying clinician who provided them with a patient information sheet and obtained verbal consent for the lead researcher to contact them. In addition, the 'Join Dementia Research' (JDR) register was also used as a recruitment tool for both samples. The JDR is a HRA endorsed online self-registration tool that enables volunteers with memory problems, carers of those with memory problems and healthy volunteers to register their interest in research. The lead researcher contacted potential participants via telephone or email. See figure 3.1 for flowchart of recruitment.

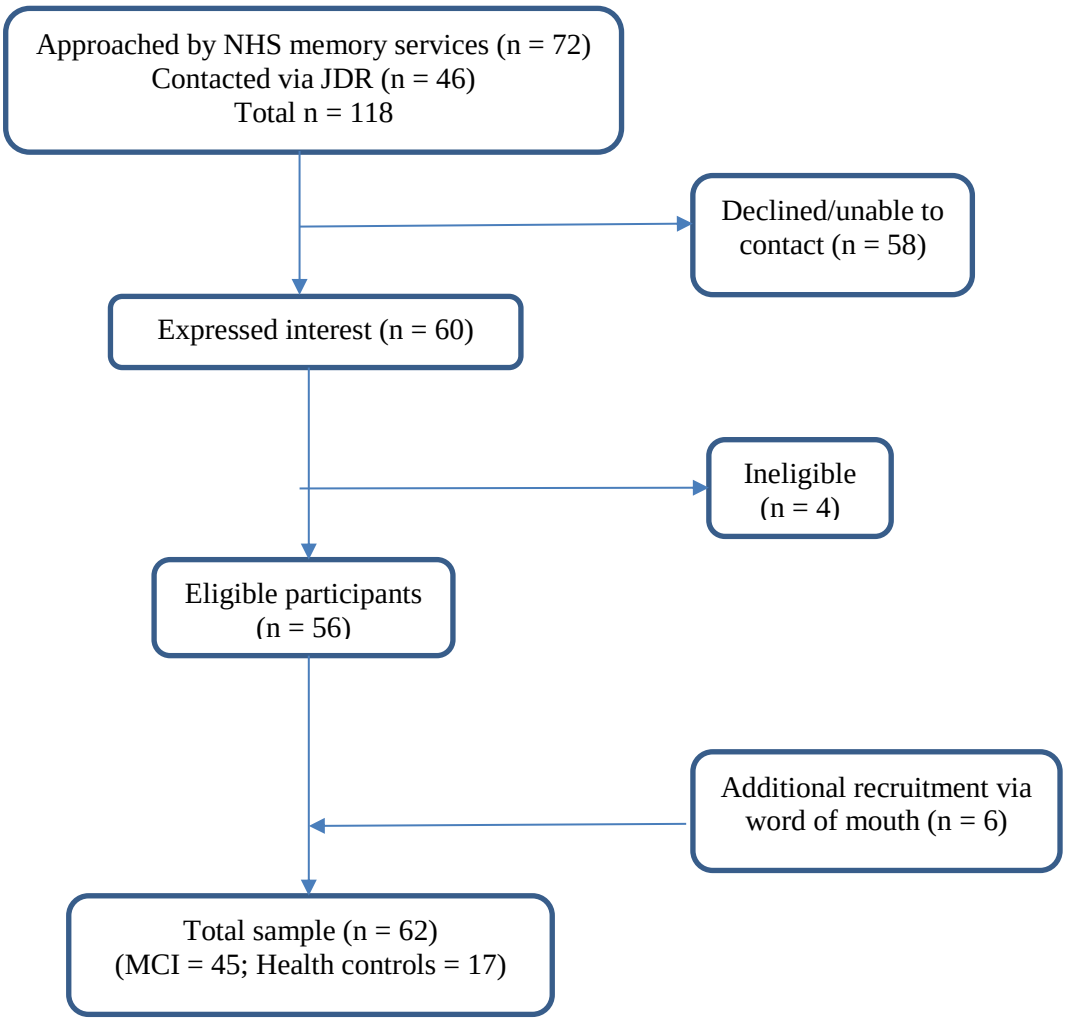

Figure 3.1: Flowchart of participant recruitment

The MCI sample was subsequently split based upon their scores on the short form Health Anxiety Inventory (SHAI). This resulted in three groups for comparison; a high HA MCI group (HiHA), low HA MCI group (LoHA) and healthy control group (HC).

Inclusion/Exclusion criteria

For the MCI sample the following inclusion criteria were applied: 1) diagnosis of MCI; 2) aged ≥50 years; 3) English speaking. The latter two criteria were also applied to the HC sample with the addition of a score ≥26 on the Montreal Cognitive Assessment (MOCA; Nasreddine et al., 2005), which acted as a screening tool to confirm the absence of cognitive impairment.

Exclusion criteria for all groups included neurological diagnoses (including a dementia), diagnosis of a significant mental health disorders (i.e. bipolar disorder, psychosis, chronic depression/anxiety disorder) and current substance dependence.

Additionally, healthy controls did not have a diagnosis of MCI or known cognitive impairment.

Measures

Short version of the Health Anxiety Inventory (SHAI)

A 14-item self-report questionnaire measuring general health-related anxiety. A cut off score of ≥18 indicates a clinical level of HA. The SHAI has good internal consistency ($\alpha = 0.89$) and scores are not elevated significantly in individuals with a physical health problem (Salkovskis, Rimes, Warwick, & Clark, 2002), an important consideration when working with an ageing population.

Illness Perception Questionnaire – Mild Cognitive Impairment (IPQ-MCI)

A recent adaptation of the IPQ –R which is adapted for use with individuals with MCI (Lin et al., 2012). The original IPQ-R is designed to be adapted for use with various illness/threats to health and has reported good reliability ($\alpha = 0.67 – 0.81$ across differing domains) and validity (Moss-Morris et al., 2002). This study utilises the consequences and causal domains of the IPQ-MCI in line with the central role of health-related attributions and catastrophising in the HA model (Salkovskis & Warwick, 1986).

Objective measures of cognitive impairment

A measure of new learning, the verbal paired associates subtest of the Wechsler Memory Scale 4th edition (WMS-IV; Wechsler, 2009), was administered by the researcher according to standardised instructions. Although it is a primary subtest of the WMS-IV, the verbal paired associates subtest can be substituted for the California Verbal Learning Test 2nd edition (CVLT-II), a list learning task, and as such its use should not interfere with clinical care. Performance on this test is likely to be in line with individuals' subjective and objective impairments and has been shown to be useful in eliciting early deficits of dementia (Bondi, Salmon, & Kaszniak, 2009).

A measure of cognitive function less commonly associated with MCI, the picture completion subtest of the Wechsler Adult Intelligence Scale 4th edition (WAIS IV; Wechsler, 2008), was also administered. Scores on this test have been shown to remain high in patients with mild to moderate dementia (Logsdon, Teri, Williams, Vitiello, & Prinz, 1989); the assumption being that it should also remain relatively intact in individuals with MCI whose cognitive impairments are mild.

Subjective measures of cognitive performance

Subjective performance is evaluated using a self-report measure in line with that used by Hayter et al (2016) & Fixter (2015). This 5-item Likert scale measures perceived performance compared to others and attribution of performance to MCI.

Quality of Life – Alzheimer's Disease scale (QOL-AD)

A 13-item rating scale administered by an interviewer according to standard instructions. Each item is rated (poor – excellent) based upon participants' responses. Although designed primarily for use with individuals with dementia, it is valid and reliable with individuals who cognitive function is mildly and moderately affected (Logsdon, Gibbons, McCurry, & Teri, 2002).

Geriatric Anxiety Inventory (GAI)

A 20-item self-report questionnaire measuring anxiety in older adults (Pachana et al., 2007). Use of a 'yes-no' format is suggested as valid for use with individuals with MCI. A cut off score of ≥9 indicates clinical levels of anxiety. Internal consistency is high ($\alpha = 0.91$).

Short form of the Geriatric Depression Scale (GDS)

A 15 item self-report questionnaire measuring depression in older adults (Yesavage et al., 1983). As with the GAI, its 'yes-no' format has been suggested to be reliable and valid in MCI. A cut of score of ≥ 5 indicates depression with ≥10 being indicative of severe depression. Internal consistency is high ($\alpha = 0.94$).

Bristol Activities of Daily Living Scale (BADLS)

A 20 item proxy questionnaire assessing functional ability across various ADLs (Bucks, Ashworth, Wilcock, & Siegfried, 1996), used in this study as a measure of disability. It is generally completed by a close relative or friend.

Procedure

Ethical approval was obtained by the NHS Health Research Authority (ref: 16/SC/0557) and subsequently by the University of Bath Psychology Ethics Committee (ref: 16-225).

All eligible participants were contacted by the lead researcher via telephone or email. Participants were offered the choice of holding the appointment at their local

memory service, the University of Bath or their own home. Appointments were completed by the lead researcher or a research assistant working in one of the recruiting memory services.

Written informed consent was obtained at the research appointment. It was made clear that participants were under no obligation to participate and had the right to withdraw at any time. Healthy controls completed the MOCA screening test first. One person was excluded on the basis of this score and their GP was contacted with their consent as per the study's ethics procedure. Participants were then asked to complete the questionnaire pack (GAI, GDS, SHAI, IPQ-MCI), structured interview (QOL-AD), cognitive tests (order of administration varied across participants) and self-ratings of performance. The control group did not complete the IPQ-MCI or a self-rating of the attribution of task performance to MCI.

All participants were asked to identify a close relative/friend to complete the BADLS. If the identified person was present at the appointment, then it was completed during this session. Otherwise the completed questionnaire was returned to the researcher by post or completed over the telephone at a later date.

Statistical Analyses

Power considerations

According to calculations performed using G*Power based on a 2x3 ANOVA, to achieve power of 0.8 with alpha of 0.05 and a large effect size (in line with Hayter et al, 2016), a sample size of 66 is necessary (i.e. 22 in each of the three groups).

Missing data

Six participants could not identify a close relative/friend who they felt comfortable asking to complete the BADLS; two from the HC group and four from the MCI group. As such six participants' data could not be included in the BADLS analyses.

Analysis

Analysis was performed using SPSS version 24. The three groups (HiHA; LoHA; HC) were compared using ANOVAs (with ANCOVAs where appropriate) for group analyses. Where effects indicated need to control for severity of impairment the WMS IV score was used as co-variate. Within subject's analyses utilised mixed model's ANOVAs, with simple main effect analyses used to interpret any significant interactions. Planned

comparisons were made. Where possible Least Significant-Difference (LSD) was used. If Levene's test for homogeneity of variance was significant, Dunnett's T3 test was used. Cohen's d was used to calculate effect size. Chi-squared analyses were used for categorical variables to investigate group differences. The alpha level was set at $p = 0.05$ for all analyses.

Results

Sample Characteristics

Demographics

As can be seen in Table 3.1, the MCI sample consisted of 16 females (35.5%) and 29 males (64.5%) with a mean age of 75.3 years (range 57 – 92; SD= 7.66). One participant identified themselves as White European; all other participants identified themselves as White British. Participants had a mean number of years in education of 13.1 years (range 9 – 23 years; SD = 3.67). Participants had a mean number of identified health problems of 1.4 (range 0 – 8; SD = 1.78).

The healthy control sample consisted of 8 females (47%) and 9 males (53%) with a mean age of 73.4 years (range 62 – 90; SD = 7.51). All participants identified themselves as White British. Participants had a mean number of years in education of 14.9 years (range 9 – 21; SD = 3.78). Participants had a mean number of identified health problems of 2.4 (range 0 – 11; SD = 2.59).

Comparison of the three groups showed no significant differences in age, ($F_{(2, 51)} = 3.04$, $p = 0.056$); gender, ($\chi^2_{(2)} = 0.70$, $p > 0.05$) and years in education, ($F_{(2, 51)} = 0.97$, $p > 0.05$). Consequently, samples were comparable on demographic characteristics.

Patient characteristics

The total MCI sample had a mean score of 8.51 (SD = 6.48) on the SHAI. For main analyses, HiHA was defined as a score of ≥ 9 and LoHA was defined as a score of ≤ 6. These cut-off values were devised through inspection of the distribution so that the point difference between groups was at least one standard error of the SHAI (SE = 1.12; (Salkovskis et al., 2002). This resulted in the removal of eight participants' data. This method was used instead of clinical cut-off values for the SHAI as insufficient participants scored in the high health anxiety range. This resulted in 18 participants in the HiHA group and 19 participants in the LoHA group. Participants who fell between these two cut offs were excluded from all other analyses. 17 healthy controls had a mean score of 8.58 on the

SHAI (SD = 6.09). Three participants (7%) in the total MCI sample and three healthy controls (18%) scored above clinical cut off on the SHAI.

There were no significant differences in general anxiety across groups as measured by the GAI ($F_{(2, 51)} = 3.16$ $p = 0.051$). Groups did differ significantly in their scores on the GDS as a measure of depression ($F_{(2, 51)} = 4.19$, $p < 0.05$). Multiple comparisons (LSD) indicated that the HiHA group scored significantly higher on the GDS as compared with LoHA and controls ($p < 0.05$), indicating lower mood in the HiHA group. There was no significant difference between the control group and the LoHA group ($p > 0.05$).

Cognitive tasks

A one-way ANOVA comparing the three groups (HiHA, LoHA, HC) on the verbal paired associates subtest of the WMS IV showed a significant main effect of group ($F_{(2, 51)} = 14.08$, $p < 0.05$). Multiple comparisons (LSD) indicated that both MCI groups (HiHA, LoHA) were not significantly different from one another ($p > 0.05$) but were significantly different from controls ($p < 0.05$), such that controls performed significantly higher than the MCI groups.

A one-way ANOVA comparing the three groups on the picture completion subtest of the WAIS IV also showed a significant effect of group, ($F_{(2, 51)} = 3.19$, $p < 0.05$). Multiple comparisons (LSD) indicated that both MCI groups (HiHA, LoHA) were not significantly different from one another ($p > 0.05$). Those with low health anxiety were significantly different from controls ($p < 0.05$) as expected. The high health anxiety group were not significantly different from controls ($p > 0.05$).

Functional impairment

In addition to objective cognitive impairment, functional impairment was also analysed given its role in the definition of MCI. A one-way ANOVA showed a main effect of group ($F_{(2, 45)} = 3.73$, $p < 0.05$). Multiple comparisons (LSD) indicated that both MCI groups (HiHA, LoHA) were not significantly different from one another ($p > 0.05$). Those with low health anxiety were significantly different from controls ($p < 0.05$) as expected. However, the HiHA group were not significantly different from controls ($p > 0.05$). Group means indicated good functionality in all three groups (LoHA = 2.94; HiHA = 3.71; HC = 0.26; Maximum score = 60).

Key Outcome Variables

Quality of Life

In the first co-primary analysis, the three groups were compared on QoL, as measured by the QoL-AD. A one-way ANOVA showed a main effect of group on QoL-AD scores ($F_{(2, 51)} = 7.15$, $p < 0.05$). Multiple comparisons (LSD) indicated that poorer QoL was a feature of the HiHA group only, who reported significantly lower scores on the QoL-AD than the LoHA group ($p = 0.001$) and healthy controls ($p < 0.05$). The LoHA and control group did not differ significantly ($p > 0.05$) (see Table 3.2). There was a large effect size ($d = 1.29$).

As planned, an ANCOVA was carried out comparing the three groups, controlling for level of cognitive impairment, as measured by verbal paired associated subtest of the WMS IV. The main effect of group was substantially unchanged ($F_{(2, 50)} = 7.31$, $p < 0.05$). Covariance adjusted QoL means for HiHA and LoHA groups were 34.66 and 41.89 respectively.

Perceived Performance

In the second co-primary analysis, perceived task performance was analysed utilising a 3 (HiHA, LoHA, HC) by 2 (performance ratings on WAIS & WMS) mixed model ANOVA. A significant main effect of task type on perceived performance was found ($F_{(1, 51)} = 10.50$, $p < 0.05$), such that participants rated their performance on the WMS IV subscale as poorer than that of the WAIS IV. A significant main effect of group on perceived performance was also found ($F_{(2, 51)} = 12.11$, $p < 0.05$), such that healthy controls rated their performance as better than both MCI groups. The interaction between group and perceived performance was not significant ($F_{(2, 51)} = 0.581$, $p > 0.05$). As such, no further analyses were conducted.

Attribution of performance to MCI

In addition to perceived performance, perceived attributions of task performance to MCI was also analysed via a 2 (HiHA, LoHA) by 2 (attribution ratings on WAIS & WMS) mixed model ANOVA. A significant main effect of task type on perceived attribution was found ($F_{(1, 35)} = 17.27$, $p < 0.05$), such that participants attributed their performance on the WMS IV to their MCI more than their performance on the WAIS IV.

Table 3.1: Means (SDs) of sample and patient characteristics, cognitive tasks and measure of functional impairment

	HC (n = 17)	***MCI (Total) (n = 45)***	***MCI (LoHA) (n = 19)***	***MCI (HiHA) (n = 18)***
Sample Characteristics	Mean (SD)	Mean (SD	Mean (SD)	Mean (SD)
Age	73.41 (7.52)	75.33 (7.67)	77.63 (6.18)	71.89 (8.26)
Gender	47% female 53% male	35.5% female 64.5% male	42% female 58% male	28% female 72% male
Years in Education	14.94 (3.78)	13.18 (3.67)	13.32 (3.42)	13.50 (4.13)
Patient Characteristics				
SHAI	8.59 (6.09)	8.51 (6.48)	3.42 (1.98)	14.22 (6.39)
GAI	2.76 (3.65)	3.49 (4.98)	1.74 (3.49)	5.50 (6.34)
GDS	2.65 (3.28)	3.64 (2.81)	2.37 (2.01)	4.89 (3.22)
Cognitive Tasks				
Paired associates (WMS IV)	29.76 (6.44)	17.38 (8.97)	14.73 (7.47)	20.22 (11.00)
Picture completion (WAIS IV)	12.12 (4.36)	9.69 (3.86)	8.68 (3.79)	10.39 (4.07)
Functional Impairment				
BADLS	0.27 (0.70)	3.62 (4.20)	2.94 (3.98)	3.71 (4.79)

There was no significant effect of group on perceived attribution ($F_{(1, 35)} = 1.31$, $p > 0.05$). The interaction between group and perceived performance was also not significant ($F_{(1, 35)} = 1.05$, $p > 0.05$).

	HC (n = 17)	***MCI (Total) (n = 45)***	***MCI (LoHA) (n = 19)***	***MCI (HiHA) (n = 18)***
	Mean (SD)	Mean (SD	Mean (SD)	Mean (SD)
QoL	41.00 (7.53)	38.20 (6.27)	41.89 (5.75)	34.67 (5.44)
Self-rating: Perceived Performance WMS	2.82 (0.53)	3.60 (0.81)	3.68 (0.67)	3.72 (0.83)
Self-rating: Perceived Performance WAIS	2.59 (0.87)	3.07 (0.69)	3.11 (0.74)	3.22 (0.55)
Self-rating: Attribution to MCI WMS	N/A	4.13 (0.69)	4.11 (0.81)	4.17 (0.62)
Self-rating: Attribution to MCI WAIS	N/A	3.60 (0.69)	3.37 (0.76)	3.72 (0.57)

Table 3.2: Means (SDs) for the key outcome variables across groups

Illness perceptions

Secondary analyses investigated the two MCI groups' (HiHA & LoHA) illness perceptions, as measured by the consequences and causes domains of the IPQ-MCI (Table 3.3). A one-way ANOVA was used to analyse the consequences domain. It showed a main effect of group ($F_{(1, 35)} = 13.44$, $p < 0.05$), such that the HiHA group scored significantly higher on the consequences domain; a higher score being indicative of greater perceived consequences of MCI.

Causal attributions were clustered according to the four causal factors identified by Moss-Morris et al (2002) with a fifth factor added, comprising of the additional causal factors introduced in the development of the IPQ-MCI (Lin et al., 2012). Due to differing numbers of items in each factor, means for each causal factor were calculated such that the groups were comparable. A 2 (HiHA, LoHA) by 5 (Causal factors 1 – 5) mixed model ANOVA found no significant effect of causal factor ($F_{(3, 104)} = 1.35$, $p > 0.05$). A significant effect of group was found ($F_{(1, 35)} = 15.74$, $p < 0.05$), such that more causal

attributions overall were made by the HiHA group. There was no significant interaction ($F_{(3, 104)} = 1.59$, $p > 0.05$).

	MCI (Total) (n = 45)	***MCI (LoHA) (n = 19)***	***MCI (HiHA) (n = 18)***
	Mean (SD	Mean (SD)	Mean (SD)
IPQ-MCI Consequences	28.47 (5.78)	25.37 (6.00)	31.56 (4.00)
IPQ –MCI Causes: Psychological attributions	12.84 (5.20)	10.79 (4.08)	15.00 (5.11)
IPQ –MCI Causes: Risk Factors	15.47 (4.95)	13.79 (4.12)	16.83 (4.62)
IPQ –MCI Causes: Immunity	5.80 (2.46)	4.58 (1.64)	7.22 (2.44)
IPQ –MCI Causes: Accident or chance	4.31 (1.70)	3.58 (1.43)	5.00 (1.75)
IPQ –MCI Causes: MCI factors	14.98 (4.92)	11.84 (3.78)	18.17 (3.60)

Table 3.3: Means (SDs) for illness perceptions (consequences & causes) across groups

Stepwise Regression Analyses

In a tertiary analysis, stepwise linear regressions were used to evaluate the relative contribution of psychological factors (SHAI, GAI and GDS) and level of impairment (WMS IV subtest) in predicting QoL, perceived task performance and illness perceptions (consequences domain) across the entire MCI group (Table 3.4). Collinearity statistics and diagnostics were conducted with no identified concerns.

For QoL, two variables entered the model. The first variable to enter was depression (GDS), accounting for 38.8% of the variance in scores on the QoL-AD (adjusted $R^2 = 0.388$, $\beta = -0.69$, $p < 0.001$). The second variable entered was the WMS IV subtest (adjusted total $R^2 = 0.511$, $\beta = -0.36$, $p = 0.001$). R^2 change attributable to the WMS IV was 0.131. For perceived performance, one variable entered the model. Actual performance on WMS IV accounted for 17.1% of the variance in perceived performance ratings on WMS IV (adjusted $R^2 = 0.171$, $\beta = -0.43$, $p < 0.05$).

Finally, for illness perceptions, one variable entered the model. General anxiety (GAI) accounted for 16% of the variance in scores on the consequences domain of the IPQ-MCI (adjusted $R^2 = 0.16$, $\beta = 0.42$, $p < 0.05$).

	B	*SE B*	*β*
QoL			
Step 1			
Constant	43.35	1.20	
GDS	-1.41	0.26	-0.63
Step 2			
Constant	48.31	1.80	
GDS	-1.51	0.24	-0.70
WMS IV subscale	-0.26	0.08	-0.37
Self-ratings of task performance			
Step 1			
Constant	4.28	0.24	
WMS IV subscale	-0.04	0.01	-0.44
Illness perceptions (consequences)			
Step 1			
Constant	26.75	0.97	
GAI	0.49	0.16	0.42

Table 3.4: Stepwise regression results for variables predicting QoL, perceived performance and illness perceptions (consequences)

Discussion

The study evaluated the impact of health anxiety in QoL, perceived performance on cognitive tasks, attribution of performance to MCI and illness perceptions. As predicted, both HiHA & LoHA groups showed more cognitive impairment than controls but did not differ from each other. High HA was associated with poorer QoL as predicted. However, contrary to prediction it was not related to perceived impairment or attribution of MCI to task performance, nor was it related to health beliefs. In additional analyses, depression and level of cognitive impairment were identified as significant predictors of QoL. Level of impairment was also a significant predictor of perceived performance. Generalised anxiety was a significant predictor of health beliefs.

Given that individuals with MCI by definition have experienced a decline in their cognitive abilities, a reduction in QoL is understandable. However, this effect was found

to be related to an individual's level of HA and was not eradicated when co-varying for actual level of cognitive impairment. This is consistent with previous studies which report an association between QoL and MCI irrespective of degree of impairment (Banerjee et al., 2009; Bárrios et al., 2013). Furthermore, the results are also in line with Hayter et al (2016) and Fixter (2015) who found a similar pattern of results in patients with RRMS and PD such that higher levels of HA were associated with significant reductions in QoL.

However, whilst the present study supports the link between HA and QoL, it differs in terms of the finding from exploratory analyses which suggested that for MCI there is an association between the individual's degree of memory impairment and depression. Although unexpected, this finding highlights a potentially important link with depression and cognitive impairment in individuals with MCI, perhaps associated with an individual's 'insight' into their difficulties. The suggested role of 'insight' was also supported by exploratory analyses which found perceived impairment to be significantly associated with actual level of impairment in the MCI sample such that participants rated their performance as poorer if their level of their impairment was more severe. The role of depression, whilst not predicted in this particular study, is in line with the suggestion that depression commonly occurs in individuals with MCI (Barnes, Alexopoulos, Lopez, Williamson, & Yaffe, 2006; Bruce et al., 2008) and supports early evidence of a relationship between depressive symptoms and health-related QoL in patients with cognitive impairments (Pusswald et al., 2016). Depression and cognitive impairment as significant factors in QoL may be attributable to insight, such that with an awareness of their declining cognitive function, comes a decline in mood. Conversely, it is worth considering whether this could also be representative of a so-called 'depressive psuedodementia' (Kiloh, 1961) sample; an important distinction worthy of further investigation given the suggestion that cognitive impairment in 'depressive psuedodementia' may be reversible secondary to treatment for depression (Muangpaisan, Petcharat, & Srinonprasert, 2012).

The present study did not replicate Hayter et al (2016) and Fixter's (2015) findings with regards to a role of HA in subjective ratings of cognitive performance, instead finding that perceived performance on cognitive tasks was associated with objective levels of cognitive impairment, suggesting it was linked to insight. However, it is inconsistent with research which suggests that individuals with MCI, whilst accurate in reporting depressive symptoms and QoL, have a tendency to under-report their level of impairment (Arlt et al., 2008).

The present study also did not replicate the relationship between HA and attribution of task performance to their health condition as per Hayter et al (2016) and Fixter (2015). However, it did find a significant effect of group on causal attributions of IPQ-MCI such that individuals with HiHA were more likely to make attributions to their health condition. This is supportive of the role of increased health-related attributions in HA in Salkovskis and Warwick's model (1986). In the absence of a significant interaction, it suggests a general increased likelihood to make attributions in MCI in the absence of specificity of type of attribution made.

Limitations

The study is limited by its' sample size such that it did achieve the planned level of power. However, the effect size of the nonsignificant effect of HA on perceived cognitive performance was very small (d = 0.05) and as such it is likely that this represents a true negative finding. The small sample size did limit the extent of the difference between the LoHA and HiHA groups, although the minimum of one standard error difference was achieved. The study was also unable to use the clinical cut offs for the SHAI due to very limited numbers of the MCI sample scoring in the clinical range for HA (7%) and it is possible that inclusion of greater numbers would have yielded a broader range of SHAI scores allowing for the use of clinical cut offs, thus creating a larger gap between LoHA and HiHA groups. Comparison with SHAI means in Fixter (2015) and Hayter et al (2016), demonstrate lower levels of HA in the MCI sample and it is possible that a sample with higher levels of HA may have strengthened the relationship with QoL. In addition, it is also worth noting that greater numbers of MCI participants (27%) scored above the clinical cut off for depression, perhaps suggesting a greater prevalence of depression in MCI.

The study also utilised a heterogeneous MCI sample with regards to type and severity of cognitive impairment as opposed to classifying the sample according to primary impairment (e.g. amnestic vs. non-amnestic). Whilst this is likely to be representative of the population receiving this diagnosis in clinical practice, it is worth considering within the context of the choice of the WMS IV as the primary measure of objective cognitive impairment. Cognitive difficulties captured by the WMS IV are likely to be more closely associated with those presenting with an amnestic MCI profile, given that this selected subscale is primarily a measure of short-term memory, specifically new learning. In addition, the role of explicit feedback in the administration of the paired associates subscale should also be considered given that results suggested good insight in

our sample contrary to other studies (Arlt et al., 2008). Whilst feedback is included in the paired associates subscale to assess new learning, it may have inadvertently aided participants in their ability to gauge their cognitive performance and replication of the study with a more ambiguous cognitive task may yield different results.

The use of stepwise regression as opposed to other forms of regression analyses may also be questioned following concerns regarding the limitations of using a stepwise approach. These concerns include the role of the variable selection method and multiple comparisons. Holding these limitations in mind, it is possible that use of a different regression analyses may have yielded different results.

Future research

Future research would benefit from further investigation into the mediating role of depression and cognitive impairment in QoL in MCI, including a qualitative exploration of the experience of QoL in MCI. More detailed investigation at the level of the individual items on the QoL-AD measure may also pose some interesting questions to be explored further. A longitudinal approach would also allow for investigation of possible causality. This is particularly pertinent giving the ongoing debate surrounding the relationship between late-life depression and cognitive impairment, including the possibility of late-onset depressive symptoms being indicative of an increased likelihood of progression of cognitive impairments to a dementia (Palmer et al., 2007) with some going as far as to suggest that depression, MCI and dementia may in fact lie on a clinical continuum (Panza et al., 2010). Investigation of the role of insight into one's cognitive impairments and its' potential relationship with psychological distress would also be beneficial.

Replication with a large sample would also be warranted to determine whether our findings are reflective of the true nature of psychological difficulties experienced in this population, such that depression may be a more pertinent issue for this population. Relatedly, looking at the prevalence rates of different psychological difficulties in an MCI population would be beneficial, particularly given recent suggestions that MCI is becoming primarily a "psychosocial issue" (Verhey & de Vugt, 2013). Clinical levels of HA were notably low in our sample (7%) and it would be worthy of investigation as to whether this was representative of the prevalence rates in this population or was instead the result of a sampling bias.

Clinical implications

The findings of this study have identified significant roles for HA and depression in QoL of individuals with MCI. As such, clinicians would benefit from the use of routine screening tools for psychological distress, particularly depression and health anxiety.

The identified role of depression and cognitive impairment in mediating QoL in MCI has important clinical implications, particularly given evidence suggesting that depression may be an early risk factor for progression to dementia (Palmer et al., 2007). Better understanding the relationship between psychological factors in this population is particularly pertinent given that all too often many individuals are left with an ambiguous diagnosis and little to no professional support. As such, further investigation of the efficacy of psychological support, e.g. cognitive-behavioural treatments, in clinical practice would be warranted. The effectiveness of such interventions in practice could be assessed via an A-B design single case series in the first instance.

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Executive Summary

Background

Mild cognitive impairment (MCI) is a common yet controversial diagnosis with marked heterogeneity in its' diagnostic criteria and clinical outcomes. This heterogeneity brings with it uncertainty and ambiguity for both the clinicians working in memory services as well as the individuals who receive this label. This study aims to investigate the extent and role of health anxiety in individuals' experiences of MCI, evaluating the impact of health anxiety (HA) on quality of life (QoL), perceived ability and health beliefs.

Method

Forty-five individuals with MCI completed questionnaires assessing HA, QoL, mood, functional ability and health beliefs. They also completed two cognitive tasks followed by self-ratings of perceived performance and attribution of their performance to MCI. Groups were compared based on their level of HA (low vs. high) and to a sample of non-impaired controls (n = 17). Participants in the MCI sample were divided into high HA and low HA groups according to their scores on the Short version of the Health Anxiety Inventory (SHAI) for subsequent analyses.

Results

As predicted, both the high heatlth anxiety MCI group (HiHA) & the low health anxiety MCI group (LoHA) showed more cognitive impairment than controls but did not differ from each other. The high HA group reported significantly reduced QoL as compared to the low HA group and healthy controls. No significant effect of HA was found on perceived performance or attribution of performance to MCI. In further exploratory analyses, depression and level of cognitive impairment were identified as significant predictors of QoL. Level of impairment was also a significant predictor of perceived performance. Generalised anxiety was a significant predictor of health beliefs.

Whilst the present study supports the link between HA and QoL as per previous research in Relapsing and Remitting Multiple Sclerosis and Parkinson's Disease, it differs in terms of the finding from exploratory analyses which suggested that for MCI at least some of these effects may be mediated by the individual's degree of memory impairment and depression. Although unexpected, this finding highlights a potentially important link

with depression and cognitive impairment in individuals with MCI, perhaps mediated by an individual's 'insight' into their difficulties.

Implications for Research

Future research would benefit from further investigation into the mediating role of depression and cognitive impairment in QoL in MCI including: a qualitative exploration of the experience of QoL in MCI; investigation at the level of the individual items on the QoL measure (QoL-AD); and a longitudinal approach to allow for investigation of possible causality/directionality in the relationship between depression and QoL in MCI.

Replication with a large sample would also be warranted to determine whether our findings are reflective of the true nature of psychological difficulties experienced in this population, such that depression may be a more pertinent issue for this population. Relatedly, looking at the prevalence rates of different psychological difficulties in an MCI population would be beneficial

Clinical Implications

Given the identified significant roles for HA and depression in QoL of individuals with MCI, clinicians would benefit from the use of routine screening tools for psychological distress, particularly depression and health anxiety. Better understanding the relationship between psychological factors in this population is particularly pertinent given that all too often many individuals are left with an ambiguous diagnosis and little to no professional support. As such, further investigation of the efficacy of psychological support, e.g. cognitive-behavioural treatments, in clinical practice would also be warranted.

Connecting Narrative

Whilst conducted across different fields, my research has primarily focused on achieving a greater understanding of the experiences of individuals facing psychological difficulties with the aim of guiding best clinical practice whilst also making a valuable contribution to the evidence base. I have conducted a critical review of the literature to gain an understanding of the role of non-fear emotions, specifically guilt and shame, in the development and maintenance of PTSD in those individuals who are traumatised by their own actions; gained clinician, patient and carer perspectives in order to understand how best to support patients with the complex decision-making process surrounding whether or not to undergo lung transplantation in Cystic Fibrosis (CF); and investigated whether greater consideration of health anxiety (HA) in older adults with Mild Cognitive Impairment (MCI) would enable us to better understand the experiences of those individuals who receive this diagnosis. Completing this research has involved consulting relevant legislation and policies, critically reviewing relevant literature, involving service users in the design and implementation of research, and conducting both qualitative and quantitative research methodology across NHS-based services.

Critical Review of the Literature

As with all of my research projects, the topic for my literature review arose from a pre-existing interest in posttraumatic stress disorder (PTSD). As an undergraduate I had completed my dissertation investigating contextual integration in information processing in PTSD and psychosis. I recall how at that time, I became fascinated with Ehlers and Clark's cognitive model of PTSD (2000) and was keen to further develop my understanding of the mechanisms of PTSD development and maintenance throughout training. This fascination was rekindled by Martina Mueller, who facilitated our PTSD teaching in our first year of the doctoral programme. Martina spoke of the many dimensions of PTSD, beyond that of the well-known fear-based model. This began to make me wonder about what the mechanisms may be in the development and maintenance of PTSD when different emotions are involved. Guilt, and particularly shame, are emotions that I also hold a particular interest in, given my experience of how powerful these emotions can be in therapy; for example, making it difficult for people to fully share the details of their experiences for fear of being judged. This felt particularly pertinent in those individuals who may in fact be judged because of the nature of their trauma, when they are traumatised by their own actions. This was something else that Martina had touched upon in our teaching and I again found myself keen to know more.

In addition to my previous research experience, my interest in this field also stemmed from personal experience. My fiancée is in the military and I have consequently developed an enthusiasm for the promotion of mental health support in military personnel and their loved ones. As an area where a substantial amount of stigma continues to exist, it felt valuable to conduct research in this field. Initially I had planned to explore the potential of conducting a main research project in the military; however, when my fiancée was told he was being sent to Afghanistan for 9 months, I decided this now felt too personal. As such, bringing this interest into my literature review felt like a more comfortable option.

From the beginning of the literature review, I quickly realised how I had underestimated the amount of time that would be involved. Having carefully defined my search terms, I felt a little shocked to have over 600 results, although I was also thankful that it was not more, knowing how others in my cohort had fell into the thousands. As I made my way through the literature, I found myself becoming increasingly enthusiastic as I discovered more and more that I didn't know. My supervisor, Ailsa Russell, was helpful at assisting me in keeping my focus and ensuring that the review question was both clearly defined and appropriately focused so that the review did not become too all-encompassing and lose its' empirical and heuristic value. We discussed the best means of synthesising what I had found, including how to analyse the information within the framework of available cognitive models as opposed to simply describing the information. Completing this review has certainly been a learning curve for me, I definitely feel my skills at searching for, synthesising, and critiquing empirical evidence have improved as a result of this process.

Service Improvement Project

Another of my pre-training interests was in clinical health, being one of the many things that attracted me to the Bath course when applying. As such, I was keen that one of my projects was in this area. My service improvement project (SIP) arose following the research fair, after I contacted a number of research supervisors who had presented research areas in clinical health. Initially, I had hoped to complete my project in a paediatric service; however, following a discussion with Samantha Phillips, the Clinical Psychologist in the Cystic Fibrosis service, who provided me with some background literature relevant to supporting lung transplant decisions in CF, I found myself intrigued to learn more.

Prior to starting training, my research experience had solely been using quantitative methodology, and I was eager to gain some experience in the qualitative field. Samantha and I discussed this as we began to shape the project together finding a way to incorporate the service need as well as my training needs and interests. Service user involvement in research, particularly at the service improvement level, is something I feel strongly about and as such I was keen to hear directly from patients in considering how best to shape the service to meet their needs. Having discussed this with Samantha, whilst she was happy for this to form part of the project, she also suggested we broaden the project to also include clinician perspectives due to a limited sample size. Being a sensitive topic for adults with CF, the service felt strongly about who they should invite to take part. Consequently, we agreed upon a clinician focus group alongside interviews open to patients and their significant others in the hope this would give us a good sample size.

Facilitating the focus group was something which I felt apprehensive about, finding public speaking and presentations to be anxiety-provoking. However, I was pleasantly surprised to find that not only did it run smoothly but there was clearly a wealth of data arising from the conversations the staff were having. Conducting the interviews was equally valuable and I remember feeling humbled by the conversations I had with the patients and their families, as it provided me with a stark reminder of the privilege of working in this role and the value that research can bring to directly improving patient experience.

Thematic analysis was unfamiliar and once again I found I underestimated the time and energy involved in this process. At this stage my internal supervisor, Liz Marks, was a considerable support agreeing to hold regular and lengthy meetings were we reviewed, re-reviewed and re-reviewed once more the coding and themes whilst navigating our way through what was a relatively novel field for us both. During this process I learnt the nuances of thematic analysis, including whether I was working from an inductive or deductive position, and discovered how the reputation that qualitative research has as the ‘easy option’ could not be further from the truth.

Main Research Project

Having previously worked as an Assistant Psychologist in a memory service for older adults, I had already been party to a number of debates between clinicians in the service regarding how best to understand and navigate the relatively recent but increasingly common diagnosis of Mild Cognitive Impairment (MCI). It had always been

a label I had felt some unease at giving, and I had been curious to understand the very different receptions that it could receive from the people to whom I was giving this feedback. To begin with I had considered the way in which I was delivering this information but soon I came to realise that the same words could be received in very different ways. Consequently, when Paul Salkovskis broached the possible role of health anxiety (HA) in MCI in our first year HA teaching, it was a research question which immediately fit with the questions I had already been posing.

In discussing the research design, Paul very helpfully shared with me some previous research which had looked at a similar role of HA in other neurological conditions; namely Multiple Sclerosis (MS) and Parkinson's disease (PD). Reading these studies alongside a review of the literature relevant to MCI, I was convinced of the heuristic value that this research could hold and felt excited at the prospect of conducting such beneficial research in a field that I already knew first hand could have very real clinical implications in the services working with these individuals.

Sadly, this excitement temporarily diminished as I navigated my way through what felt like a never-ending climb up a mountain of NHS ethics. Having never completed an IRAS form before, the endless pages of questions felt like an uphill struggle at times. Combined with a change in the HRA procedures amidst this process as well as navigating two Research and Development (R&D) ethics procedures too, there were certainly times when I questioned whether this was all worth it. However, as I emerged from the ethics battle a conqueror my excitement and passion for the research quickly returned.

Due to the nature of my research measures, my research meant that face to face appointments were the only option. This was a huge source of frustration at times when completing research as part of a doctoral training course that already has such significant time pressures on you. I was extremely lucky to have the support of my external supervisor, Orazio Giuffrida's Assistant Psychologist, Chloe, who supported me during the recruitment and data collection stages of the research. In addition, working with Chloe also provided me with some valuable supervisory experience. Whilst my frustration was there, meeting with the participants face to face also became a huge driving force to keep me motivated to continue on as research fatigue set in. The process provided me with opportunity after opportunity to meet such kind and accommodating participants who received my research with such enthusiasm and gratitude that I felt compelled to work through the stress.

I am enormously grateful for Paul's support and guidance during the navigation of statistical analyses, booking regular meetings into his already full diary to help me remain on the right track. The primary statistical analyses I used were familiar to me having completed ANOVAs and ANCOVAs in my undergraduate research and this certainly helped, not being particularly fluent in the art of statistical analyses or SPSS. Seeing the hard work come together in the interpretation of and reflection on the results brought with it a sense of achievement and I found myself invested in my research and keen to increase my numbers that bit further in order to put forward for publication at a later date.

Case Studies

Completing a case study on each of my four core placements and my first elective placement has been a hugely valuable experience in reflecting on both the professional role of therapy, as well as the personal impact that working with individuals with psychological difficulties can have on the training experience and personal development. Whilst a daunting process, I always commented on how I found the process of writing up a case study to be somewhat therapeutic for me as it brought together the work that we had done and was a means of keeping me in touch with the evidence-base and the its' role in guiding our work with individuals, being the foundation of the therapeutic work that we do.

However, writing the case studies was not without its challenges. Ensuring that the case studies met the requirements of the course, particularly the BABCP requirements, could at times feel like you were slightly fitting a person into a therapy mould rather than being truly guided by their experiences in developing a collaborative formulation. In this way, they also emphasised the delicate balancing act that comes with ensuring that you work with the individual formulation and experience as well as the evidence-base. As a result of the BABCP requirements, I have finished with all five of my case studies being in the field of cognitive-behavioural approaches and whilst I feel each one was valuable and enjoyed writing them, I would have liked to have had a case study written from a different perspective. I have been able to address this somewhat in presenting an integrative case study which involves not only transdiagnostic elements of CBT but also third-wave and compassion-focused approaches. I also extended my case study portfolio by writing up a group case study on my elective as a change from the individual case studies from my core placements.

Completing case studies also highlighted to me the importance of using routine outcome measures in your work, both as an evaluative tool as well as a therapeutic one. In the context of working in services where routine outcome measures were not the norm, as well as working with individuals for whom it was important that they held meaning and were comprehendible (for example, having to create idiosyncratic measures on my learning disabilities placement), this was a challenge at times and I sometimes felt frustrated. However, on reflection I can now see the benefit of their use and have already discussed on my current placement the possibility of introducing routine outcome measures as a means of service improvement alongside aiding clinicians in evaluation of their work.

Future Research Plans

After coming into training with minimal research skills as compared with my clinical experience and with little enthusiasm for working in a research environment, my research experiences have shifted this perspective. I can now see more clearly the value of being involved in research and the crucial role it has in our profession. I am already using the research skills I have developed on my final placement, working alongside my supervisor and the team manager to explore the introduction of outcome measures into the service, as well as discussing with a colleague who is also involved in the Thrive project in schools how they could evaluate the fantastic work that they are doing to disseminate this message more widely.

Consequently, I now feel confident that my research career will continue (although perhaps completing fewer projects at any one given time!). I feel particularly passionate about the relationship between research and clinical practice and the role that this can have in shaping service improvement. I also hugely valued the experience of completing qualitative research as a means of involving service users more in service development and improvement and would be keen to do further qualitative research in my future career. Finally, I have learnt the value of single case studies and plan to continue to use routine outcome measures in my clinical work so that important lessons can be learnt from those single cases. I feel very proud to have had one of my case studies accepted as a poster at the BABCP conference this year and this has highlighted to me that these smaller scaled projects have value too. To say I am a complete convert would be an exaggeration but I now look forward to finding means of keeping research alive as I enter the world of qualified life in busy NHS services and feel the skills I have gained mean that I am now in the best position possible to do so.

Appendix A: Currier et al (2013) Regression Model (Guilt-based)

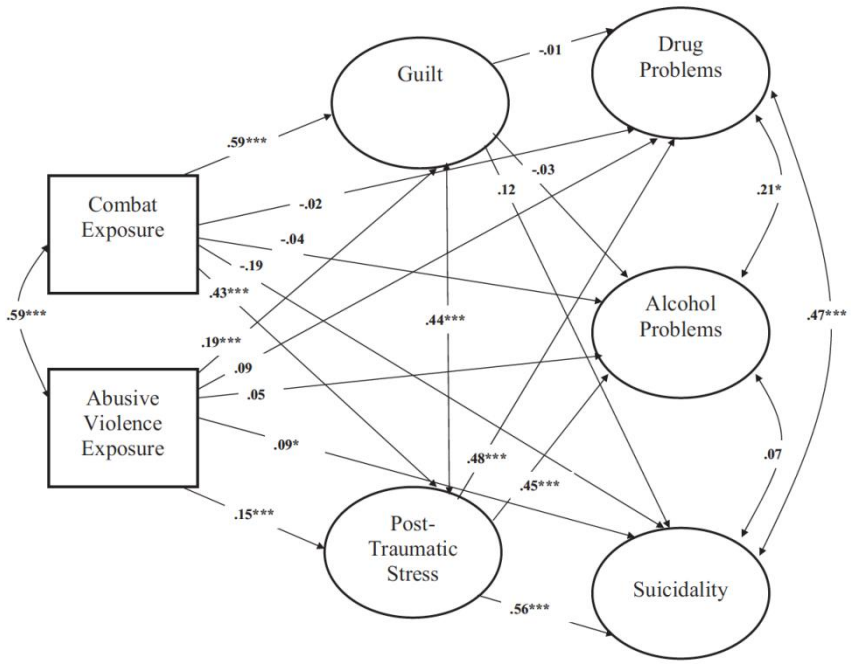

Figure 1. Pictorial representation of the structural equation model with standardized estimates. $^{*}p < .05$. $^{**}p < .01$. $^{***}p < .001$.

Appendix B: Dennis et al (2016) Regression Model (Guilt-based)

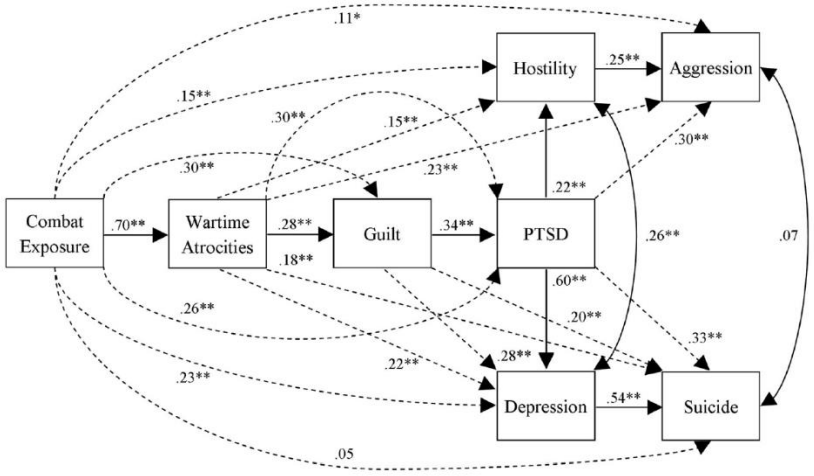

Figure 2. Path analysis model of influence of involvement in wartime atrocities on PTSD, aggression, and suicide. Solid lines represent direct effects after controlling for predictors entered earlier in the model. Dashed lines represent unadjusted direct effects (i.e., direct effects not statistically adjusting for potential mediators/subsequently entered predictors). Numerical values are standardized effects. $^{*}p < .05$, $^{**}p < .01$. $N = 599$.

Appendix C: Marx et al (2010) Regression Models (Guilt-based)

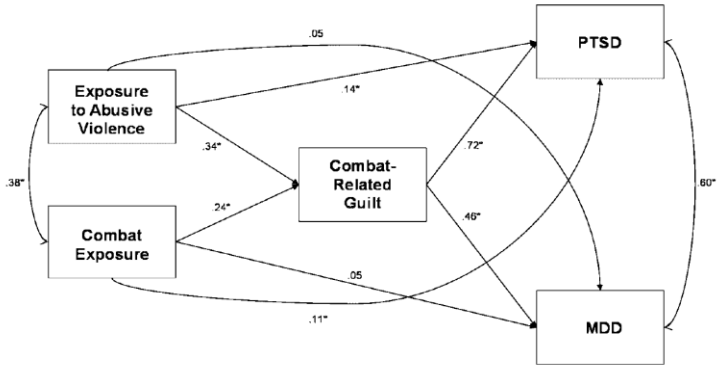

Figure 1. The direct effects among exposure to combat-related abusive violence and combat exposure relative to no exposure to combat-related abusive violence, combat-related guilt, PTSD, and MDD. PTSD, Posttraumatic Stress Disorder; MDD, Major Depressive Disorder; All numerical values represent completely standardized coefficients, *($P<.001$). Sample size for Model 1 was 1,323.

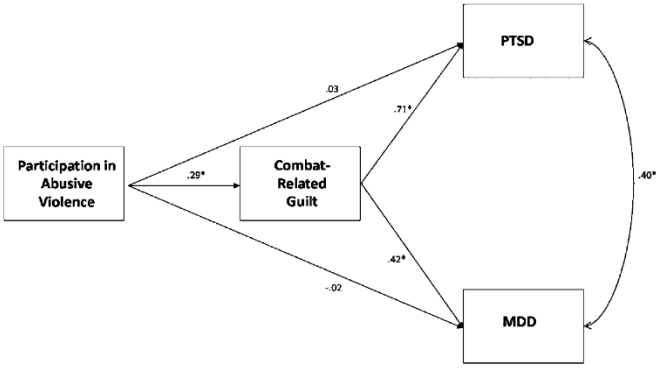

Figure 2. The direct effects among participation relative to observation of combat-related abusive violence, combat-related guilt, PTSD, and MDD. PTSD, Posttraumatic Stress Disorder; MDD, Major Depressive Disorder; All numerical values represent completely standardized coefficients, *($P<.001$). Sample size for Model 2 was 757.

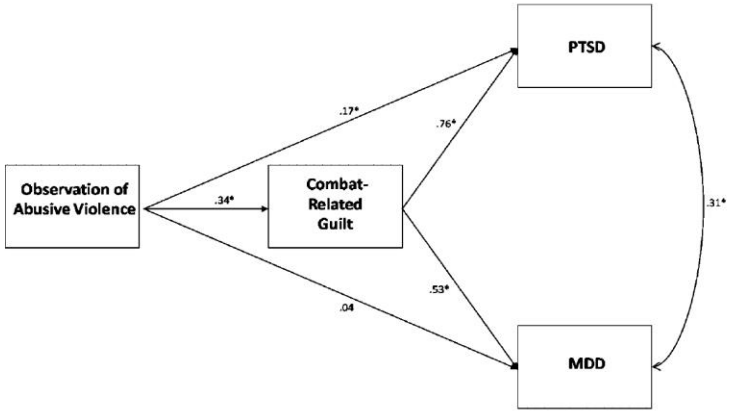

Figure 3. The direct effects among observation relative to no exposure of combat-related abusive violence, combat-related guilt, PTSD, and MDD. PTSD, Posttraumatic Stress Disorder; MDD, Major Depressive Disorder; All numerical values represent completely standardized coefficients, *($P<.001$). Sample size for Model 3 was 871.

Appendix D: Jordan et al (2017) Regression Model (Guilt & Shame-based)

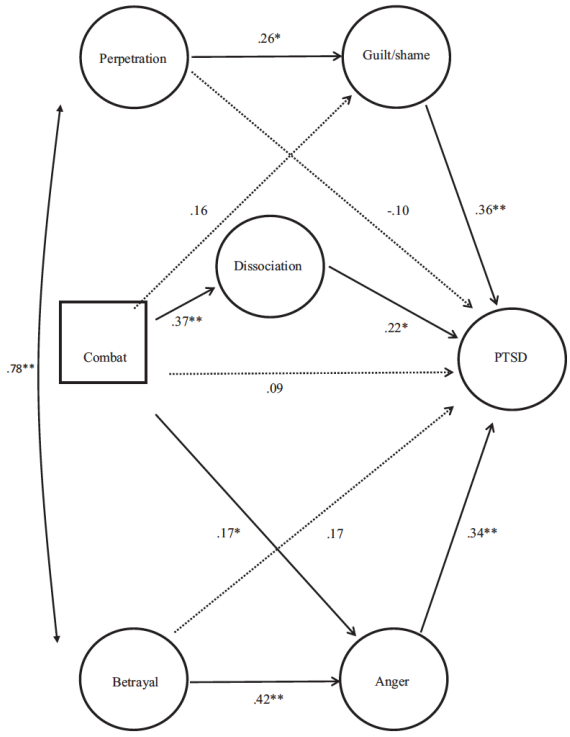

Figure 1. Unidirectional arrows are standardized path coefficients. * $p < .05$, ** $p < .01$.

Appendix E: Sippel & Marshall (2011) Regression Model (Shame-based)

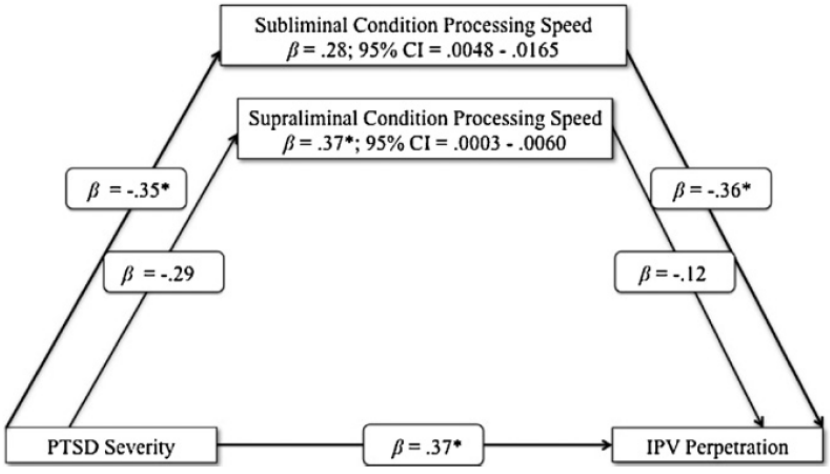

Fig. 1. Mediating effect of shame processing speed on the relation between PTSD severity and IPV perpetration frequency. IPV = intimate partner violence; β = standardized beta; CI = confidence interval. *$p < .05$, **$p < .01$, all one-tailed.

Appendix F: Clinical Psychology Review Author Guidelines

Peer review

This journal operates a single blind review process. All contributions will be initially assessed by the editor for suitability for the journal. Papers deemed suitable are then typically sent to a minimum of two independent expert reviewers to assess the scientific quality of the paper. The Editor is responsible for the final decision regarding acceptance or rejection of articles. The Editor's decision is final. More information on types of peer review.

Use of word processing software

It is important that the file be saved in the native format of the word processor used. The text should be in single-column format. Keep the layout of the text as simple as possible. Most formatting codes will be removed and replaced on processing the article. In particular, do not use the word processor's options to justify text or to hyphenate words. However, do use bold face, italics, subscripts, superscripts etc. When preparing tables, if you are using a table grid, use only one grid for each individual table and not a grid for each row. If no grid is used, use tabs, not spaces, to align columns. The electronic text should be prepared in a way very similar to that of conventional manuscripts (see also the Guide to Publishing with Elsevier). Note that source files of figures, tables and text graphics will be required whether or not you embed your figures in the text. See also the section on Electronic artwork.

To avoid unnecessary errors you are strongly advised to use the 'spell-check' and 'grammar-check' functions of your word processor.

Article structure

Manuscripts should be prepared according to the guidelines set forth in the Publication Manual of the American Psychological Association (6th ed., 2009). Of note, section headings should not be numbered.

Manuscripts should ordinarily not exceed 50 pages, *including* references and tabular material. Exceptions may be made with prior approval of the Editor in Chief. Manuscript length can often be managed through the judicious use of appendices. In general the References section should be limited to citations actually discussed in the text. References to articles solely included in meta-analyses should be included in an appendix, which will appear in the on line version of the paper but not in the print copy. Similarly, extensive Tables describing study characteristics, containing material published elsewhere, or

presenting formulas and other technical material should also be included in an appendix. Authors can direct readers to the appendices in appropriate places in the text.
It is authors' responsibility to ensure their reviews are comprehensive and as up to date as possible (at least through the prior calendar year) so the data are still current at the time of publication. Authors are referred to the PRISMA Guidelines (http://www.prisma-statement.org/statement.htm) for guidance in conducting reviews and preparing manuscripts. Adherence to the Guidelines is not required, but is recommended to enhance quality of submissions and impact of published papers on the field.

Appendices

If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on. Similarly for tables and figures: Table A.1; Fig. A.1, etc.

Essential title page information

Title. Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible. **Note: The title page should be the first page of the manuscript document indicating the author's names and affiliations and the corresponding author's complete contact information.**

Author names and affiliations. Where the family name may be ambiguous (e.g., a double name), please indicate this clearly. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lower-case superscript letter immediately after the author's name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name, and, if available, the e-mail address of each author within the cover letter.

Corresponding author. Clearly indicate who is willing to handle correspondence at all stages of refereeing and publication, also post-publication. **Ensure that telephone and fax numbers (with country and area code) are provided in addition to the e-mail address and the complete postal address.**

Present/permanent address. If an author has moved since the work described in the article was done, or was visiting at the time, a "Present address"' (or "Permanent address") may be indicated as a footnote to that author's name. The address at which the author actually

did the work must be retained as the main, affiliation address. Superscript Arabic numerals are used for such footnotes.

Abstract

A concise and factual abstract is required (not exceeding 200 words). This should be typed on a separate page following the title page. The abstract should state briefly the purpose of the research, the principal results and major conclusions. An abstract is often presented separate from the article, so it must be able to stand alone. References should therefore be avoided, but if essential, they must be cited in full, without reference to the reference list.

Graphical abstract

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Appendix G: SIP Focus Group and Interview Material

Evaluating need for a lung transplantation decision aid tool in an NHS Cystic Fibrosis service

Rachel Phillips
Clinical Psychologist in training
University of Bath

Decision Aid Tools – The Evidence Base

- 80 RCTs supporting the efficacy of patient decision aid tools (PtDAs) in supporting complex decision making in chronic physical health conditions (O'Connor et al, 2009)
- Coulter (2013) – review of the literature suggested the following benefits:
  - Addressing inadequate knowledge & unrealistic expectations
  - Reducing unwanted pressure and increasing support
  - Supporting shared decision making

Lung transplant in CF study – Vandemheen et al, 2009

- Single blind RCT – 148 adults with CF
- Standardised questionnaires: pre (baseline), post (3wks) & 1yr follow up
- PtDA presented as an online tool (http://decisionaid.ohri.ca/decaids.html) & a paper copy
- PtDA as a beneficial adjunct to care as usual:
  - Reduced decisional conflict
  - Increased patient knowledge and understanding of the procedure, process and associated risks
  - Facilitated more realistic expectations
  - Improved patient satisfaction
- No difference in stated choice or durability of choice

Application to Clinical Practice

- O'Connor (1998) – importance of considering clinical characteristics such as patient and provider perceptions at the earliest stage of PtDA development
- Montori et al (2007) – the recognition of patient's and clinicians' needs are crucial in ensuring that PtDAs have the desired effect on decision making
- Coulter et al (2013) – without these considerations, services are suggested to be at risk of causing harm as opposed to improving care

Discussion

What are your views on the current service provision for supporting individuals with decisions regarding lung transplantation?

Do you think there is a place in the service for the introduction of a decision aid tool for lung transplant?

Discussion

In your view, what may the benefits of introducing a decision aid tool be for:
- service users and their families?
- staff?
- service delivery?

Would you have any concerns about the introduction of a decision aid tool for:
- service users and their families?
- staff?
- service delivery?

Discussion

- **Using the example decision aid tool as a guide, what adjustments, if any, do you think would need to be made to ensure this was meaningful to your service?**
- **What do you like about this example?**
- **What do you dislike about this example?**

Discussion

If a decision aid tool were to be introduced into the service, how do you think it should be delivered?

For example,
- **to whom should it be made available?**
- **at what stage of the treatment pathway should it be made available?**
- **how should this be introduced to individuals and their families and by whom?**
- **in what modality should it be presented (e.g. paper, online, mobile apps)?**

Contact Details

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Appendix H: Example PtDA (Vandenheem et al, 2009) given to participants

When your lung function is getting worse...

Should you be referred for a lung transplant?

A decision aid for adults with cystic fibrosis

This decision aid is for you if you have cystic fibrosis and:

- You are 18 years and older
- Your lung function has been getting worse (less than or equal to 40% of normal)
- You want to think about future options when your lungs don't work enough to keep you alive

What is cystic fibrosis (CF)?

It is a genetic disease that affects many body systems. It causes the body to produce abnormally thick, sticky mucous that is difficult to clear. This mucous traps bacteria and leads to chronic infection that damages the lungs. The mucous makes it difficult for air to move in and out of the lungs and causes shortness of breath. It can also cause problems in the liver, pancreas, and with digestion. In Australia, half of the patients with CF live beyond 34 years of age. Most people with CF die of lung disease.

When CF gets worse...

As time goes by, you may have more frequent chest infections and more trouble with your breathing. The infections cause a decline in your lung function. Generally when your lung function is less than 30% of normal your doctor would consider referring you for lung transplantation. At this time, your expected survival without transplantation is approximately 2-3 years.

We realize that you may be reviewing this material when your lungs are still working well enough and lung transplantation is not something you will need in the near future. However, most patients with CF eventually have to consider this option at some point.

What are your options?

- Not to be referred for lung transplantation.
- To be referred for lung transplantation.

Working through the 5 steps of this decision aid will help you decide.

Step 1: Think about how CF affects you now.

How does CF affect your life? Check ☑ any of these that apply.

Breathing
- ☐ shortness of breath
- ☐ coughing
- ☐ coughing up blood
- ☐ coughing up phlegm
- ☐ frequent chest infections
- ☐ frequent hospitalizations

Daily Activity and Lifestyle
- ☐ cannot work or go to school or reduced working hours
- ☐ difficulty maintaining weight
- ☐ less energy
- ☐ difficulty with daily activities (e.g. bathing, preparing meals)
- ☐ short of breath when walking or exercising
- ☐ increasing fatigue

Emotional
- ☐ feeling anxious
- ☐ feeling scared
- ☐ feeling depressed or unable to cope
- ☐ feeling angry or irritable

Social
- ☐ being unable to participate in social activities with family and friends
- ☐ feeling embarrassed in public because of coughing and sputum production
- ☐ feeling isolated

What are you doing to manage your CF? Check ☑ any of these that apply.

Breathing
- ☐ bronchodilators (e.g. ventolin, serevent or oxeze)
- ☐ inhaled antibiotics (e.g. tobramycin, colistin)
- ☐ anti-inflammatories (e.g. ibuprofen, flovent, pulmicort)
- ☐ mucus-thinning agents (e.g. pulmozyme, hypertonic saline)
- ☐ antibiotics
- ☐ oxygen

Daily Activity and Lifestyle
- ☐ regular exercise
- ☐ nutrition supplements (e.g. ensure, sustagen, resource, scandishake)
- ☐ pancreatic enzyme supplements
- ☐ chest physio
- ☐ tube feeding

Emotional
- ☐ talking about feelings with family, friends and CF team
- ☐ taking things one day at a time
- ☐ praying, seeking spiritual support

Alternative Therapy
- ☐ herbal medicine
- ☐ acupuncture
- ☐ massage therapy
- ☐ chiropractor

Step 2: Think about the options, benefits, and risks.

What are the options?

1. Not to be referred for lung transplantation

- You will continue to receive the same care that you have now.
- You need to understand that if lung function has fallen to less than 30% of normal then 50 in 100 patients will die within 2-3 years and 50 in 100 will be alive.
- You will continue with your usual day to day activities (work, school) as long as possible.
- As your shortness of breath gets worse you may need more aggressive and frequent treatment with oxygen, antibiotics, and chest physiotherapy and you may require more frequent hospitalization.
- Eventually, your breathing will become more laboured. At this point, to help ease your shortness of breath you will be treated with oxygen and/or a face mask breathing machine (BiPAP). If you have pain or severe shortness of breath you will be treated with medications to help ease the discomfort.
- The goal is not to cure, but to provide comfort and maintain the highest possible quality of life for as long as possible.

2. To be referred for lung transplantation

First assessment with the transplant team	**Average time is 3-5 days**	○ You go to a transplant center in Brisbane, Sydney, Perth, or Melbourne to see if you are eligible for lung transplant. ○ You have tests of the lung, heart, kidney and liver. ○ You see the transplant team. You may see the social worker, psychologist, and psychiatrist to assess whether you and your family have the financial and emotional support to cope with the stress of the transplant. ○ At the completion of the assessment, the transplant team discusses your test results with you and your family. ○ If you are eligible but not sick enough, you will return home and the transplant team will monitor your health every 3 – 6 months until they think you should go on the transplant list.
Being put on the transplant list	**Average time on the transplant waiting list is 6-12 months**	○ When you are eligible and sick enough, you are put on the lung transplant list. You will need to carry a pager or cell phone 24 hours a day and you and your family will need to live within 2 hours of the transplant centre while waiting for your new lungs. ○ Unfortunately some people die while waiting for a lung transplant.
Lung transplant surgery	**Average time in surgery is 4- 8 hours** **Average stay in ICU after surgery is 1-4 days** **Average time in hospital after surgery is 1- 4 weeks**	○ Your new lungs will come from a person who has recently died and their family has agreed to donate their lungs for transplant. You will require a general anaesthetic for the surgery. Your diseased lungs will be removed through a large chest incision. ○ You will wake up in the intensive care unit with a breathing tube in your windpipe and you will be on a mechanical ventilator (machine that helps you breathe) for 1 – 3 days. You will have tubes in your chest (chest tubes) and lines in your arms (intravenous) and wrist (arterial).
After hospital	**Average time is 3-6 months**	○ You will have to live in or very near your transplant center for several months after your transplant.

After successful lung transplantation You will no longer need to do chest physiotherapy, take nebulized antibiotics, or use supplemental oxygen. You will be required to take multiple pills (at least 6 types) for the rest of your life to help reduce infection and reduce the risk of your body rejecting your new lungs.

Although your lungs will be healthier, you will still have CF. Lung transplant will not fix other CF health problems like diabetes, digestive problems, osteoporosis or male infertility.

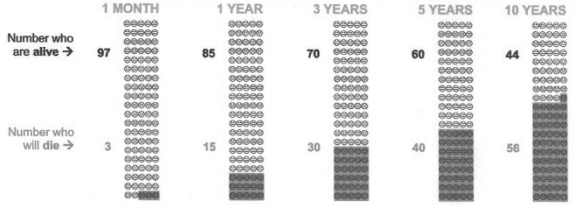
Step 2: Think about the benefits and risks.

A) What does the research show?

There are no clinical trials comparing options. Study results are based on cases of what happened to someone who had one of the options.
Blocks of 100 faces show the 'best estimate' of what happens to 100 people **with cystic fibrosis who choose different options.** Each face (☺) stands for one person. There is no way of knowing for certain what will happen to you.

Expected Results for Those Who Decline Lung Transplantation [only 1 time period known]

Expected Results After Lung Transplantation



B) What do you think of the benefits and risks of the options?

1. Review the common benefits (reasons to choose) and risks and side effects (reasons to avoid).
2. Add any other reasons that matter to you.
3. Show how much each reason matters to you. Circle one (★) star if it matters a little and up to five (★★★★★) stars if it matters a lot. Do not circle any stars if it does not matter

Reasons to Choose			
No referral for lung transplant	**How much does it matter to you?**	**Referral for lung transplant**	**How much does it matter to you?**
You avoid the ○ early risk of death from transplant [3 in 100] and the ○ long term chance of chronic problems ○ rejection [50 in 100] ○ diabetes [5-10 in 100] ○ cancer [4-5 in 100] ○ kidney failure [1-2 in 100]		You have a better chance [70 in 100] of surviving for 3 years or longer if you have a transplant compared to no transplant [50 in 100]	
You avoid the hassle, stress, and worry of ○ new care team ○ extra tests ○ being on the waitlist ○ surgery, pain and discomfort in hospital ○ recovery ○ taking multiple pills to avoid rejection ○ possible stay in another city		You are likely to be less short of breath soon after a transplant. You may feel better with new lungs and you may: ○ breathe easier with less cough ○ be able to exercise and go back to work or school ○ have more energy ○ be able to reach goals and dreams ○ spend less time on intensive treatment than would be needed if you had your own lungs [oxygen, antibiotics, chest physio, hospital stays]	
Other reasons:		Other reasons:	

Which option do you prefer? Check ☑ the option that applies.

☐ Not to be referred for lung transplant ☐ I am unsure ☐ To be referred for lung transplant

Step 3: Choose the role you prefer in decision making.

Check ☑ one.

☐ You prefer to choose on your own after hearing the views of others
☐ You prefer to share the choice with: _____
☐ You prefer that someone else chooses for you, namely: _____

Step 4: Find out what else you need to prepare you for decision making.

Please answer the questions below.
If you answer 'No' to the questions, discuss them with your doctor.

		Yes	No
Knowledge	Do you know which options are available to you? Do you know both the benefits and risks of each option?	☐ ☐	☐ ☐
Values	Are you clear about which benefits and risks matter most to you?	☐	☐
Support	Do you have enough support and advice from others to make a choice? Are you choosing without pressure from others?	☐ ☐	☐ ☐
Certainty	Do you feel sure about the best choice for you?	☐	☐

Decisional Conflict Scale © A O'Connor 1993, Revised 2004

Find out how well this decision aid helped you learn the key facts.

Check ☑ the best answer. Answers are in Appendix B.

a. Which option has the greatest chance of relieving advanced CF lung symptoms [such as shortness of breath, cough, low energy and poor exercise ability]?
☐ Lung transplant ☐ Not having lung transplant ☐ Both are about equal ☐ I am unsure

b. Which option has the greatest chance of chronic complication at 5 years [such as diabetes, cancer, kidney failure]?
☐ Lung transplant ☐ Not having lung transplant ☐ Both are about equal ☐ I am unsure

c. If 100 people with cystic fibrosis decide not to be referred for lung transplant, about how many will be alive in 2 to 3 years?
☐ between 1 and 10 people will be alive
☐ between 11 and 40 people will be alive
☐ between 41 and 60 people will be alive
☐ between 61 and 100 people will be alive
☐ I am unsure

d. If 100 people with cystic fibrosis have lung transplantation, about how many will be alive in 3 years?
☐ between 1 and 10 people will be alive
☐ between 11 and 40 people will be alive
☐ between 41 and 60 people will be alive
☐ between 61 and 100 people will be alive
☐ I am unsure

Step 5: Plan the next steps

List plans, for example: show your balance scale and responses to your doctor and/or family; learn more about the options.

Should you be referred for a lung transplant? (1 page summary)

Step 1: How CF affects me.

Breathing	☐ short of breath ☐ cough ☐ cough blood ☐ cough phlegm ☐ frequent chest infections ☐ frequent hospitalizations	☐ bronchodilators ☐ anti-inflammatories ☐ antibiotics ☐ inhaled antibiotics ☐ mucus-thinning agents ☐ oxygen	☐ herbal medicine ☐ acupuncture ☐ massage therapy ☐ chiropractor
Daily activity	☐ cannot work or go to school or reduced working hours ☐ difficulty with daily activities ☐ difficulty maintaining weight ☐ short of breath when walking or exercising ☐ less energy ☐ increasing fatigue	☐ regular exercise ☐ nutrition supplements ☐ pancreatic enzyme supplements ☐ chest physio ☐ tube feeding ☐ talking about feelings with family, friends & CF team	
Emotional	☐ feeling anxious ☐ feeling depressed or unable to cope ☐ feeling scared ☐ feeling angry or irritable	☐ taking things one day at a time ☐ praying, seeking spiritual support	
Social	☐ unable to participate in social activities ☐ feeling isolated ☐ embarrassed in public because of cough and sputum		

Step 2: My opinion of the options, benefits, and risks.

Reasons to Choose			
No referral for lung transplant	**How much it matters**	**Referral for lung transplant**	**How much it matters**
You avoid the early risk of death from transplant [3 in 100] and the long term chance of chronic problems such as rejection [50 in 100]; diabetes [5-10 in 100]; cancer [4-5 in 100]; kidney failure [1-2 in 100]		You have a similar chance [70 in 100] of surviving for 3 years or longer if you have a transplant compared to no transplant [50 in 100]	
You avoid the hassle, stress, and worry of new care team extra tests being on the waitlist surgery, pain and discomfort in hospital recovery taking multiple pills to avoid rejection possible stay in another city		You are likely to be less short of breath soon after a transplant. You may feel better with new lungs and you may: breathe easier with less cough; be able to exercise and go back to work or school; have more energy; be able to reach goals and dreams; spend less time on intensive treatment than would be needed if you had your own lungs	
Other reasons:		Other reasons:	

Which option do you prefer?

☐ Not to be referred for lung transplant ☐ I am unsure ☐ To be referred for lung transplant

Step 3: The role you prefer in decision making.

☐ You prefer to choose on your own after hearing the views of others
☐ You prefer to share the choice with:
☐ You prefer that someone else chooses for you, namely:

Step 4: Find out what else you need to prepare you for decision making.

		Yes	No
Knowledge	Do you know which options are available to you?	☐	☐
	Do you know both the benefits and risks of each option?	☐	☐
Values	Are you clear about which benefits and risks matter most to you?	☐	☐
Support	Do you have enough support and advice from others to make a choice?	☐	☐
	Are you choosing without pressure from others?	☐	☐
Certainty	Do you feel sure about the best choice for you?	☐	☐

How well this decision aid helped you learn the key facts.

a. Which option has the greatest chance of relieving advanced CF lung symptoms
☐ Lung transplant ☐ Not having lung transplant ☐ Both are about equal ☐ I am unsure

b. Which option has the greatest chance of chronic complication at 5 years
☐ Lung transplant ☐ Not having lung transplant ☐ Both are about equal ☐ I am unsure

c. If 100 people with cystic fibrosis decide not to be referred for lung transplant, about how many will be alive in 2 to 3 years?
☐ between 1 and 10 ☐ between 11 and 40 ☐ between 41 and 60 ☐ between 61 and 100 ☐ I am unsure

d. If 100 people with cystic fibrosis have lung transplantation, about how many will be alive in 3 years?
☐ between 1 and 10 ☐ between 11 and 40 ☐ between 41 and 60 ☐ between 61 and 100 ☐ I am unsure

Step 5: Next steps

Print this one page summary to keep a record of your answers and track your decision over time.

Appendix A: Information about the authors

Content Editors:
Kathy Vandemheen RN BScN*, Shawn Aaron MD MSc FRCPC*, Elizabeth Tullis MD FRCPC**, Charles Poirier MD FRCPC***

Professional Reviewers:
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*** Centre Hospitalier de L'Universite de Montreal, Canada
+ University of Alberta, Canada
++ University of British Columbia, Canada
+++ Dalhousie University, Canada
++++ London Health Science Centre, Canada
& The Prince Charles Hospital, Brisbane, Australia
&& Royal Prince Alfred Hospital, Sydney, Australia

Funder: Australian CF Research Trust
Physician Services Foundation Incorporated and Ontario Thoracic Society

Date: September 2009
Next update due 2011

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Appendix B: Answers to questions in Step 4

a. lung transplant
b. lung transplant
c. between 41-60
d. between 61-100

Back to Step 4

Glossary

Kidney Failure. Kidney failure is when your kidneys lose their ability to perform their main function of taking excess fluid and waste material from your blood. Loss of kidney function that develops gradually over time is called chronic kidney failure. Patients who suffer bad kidney failure may need to go on dialysis.

Diabetes. Diabetes or elevated sugar levels may develop after transplantation because of the medications that you are required to take. If diabetes develops after transplant you may need to go onto insulin injections.

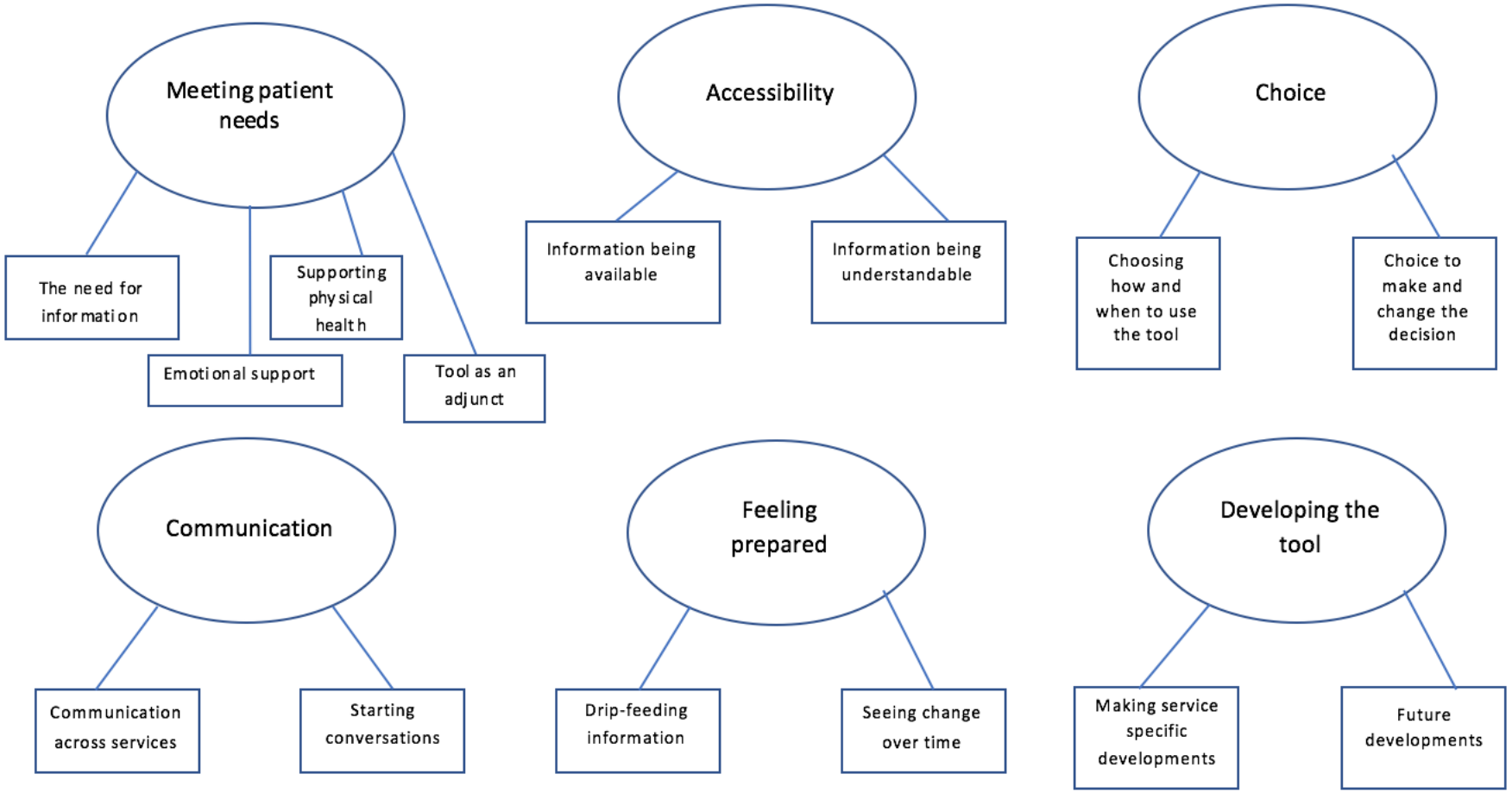
Chronic Rejection. Chronic rejection is when your transplanted lungs gradually stop working. This can cause gradual worsening shortness of breath. In extreme cases chronic rejection will lead to death or the need for a second lung transplant.

What it means to answer 'no' to the questions in **Step 4** asking about what else you need. The more **'no'** answers a person has, the more likely they are to delay their decision, change their mind, be dissatisfied with their choice, express regret with the decision they made, and blame their doctors for bad outcomes. Therefore it is important to discuss your needs with your doctor and others so that you answer **'yes'** to most questions.

Go back to where you were

This decision aid is being tested to see if it meets the International Patient Decision Aid Standards (IPDAS) Collaboration global standards (http://ipdas.ohri.ca).

Appendix I: Service Improvement Project Thematic Map



Appendix J: Service Improvement Project Patient Information Sheet (Patient & Family)

Evaluating the need for a lung transplantation decision aid tool in an NHS Cystic Fibrosis (CF) service

We would like to invite you to take part in our service improvement project. Please take your time to read this information sheet and feel free to talk it through with others before you make a decision should you so wish.

What is the purpose of the project?

The project is a service development project which aims to evaluate the support people with CF and their significant others receive from Bristol Adult Cystic Fibrosis Service when they are considering whether to have a lung transplant, and to explore whether the introduction of a patient decision aid tool would improve this. Patient decision aid tools are specially designed information resources that help individuals make difficult decisions about their health and treatment options.

Why have I been invited?

You have been invited to take part because you or your relative/friend are either on the waiting list for or have recently undergone a lung transplant as treatment for CF and are under the care of Bristol Adult Cystic Fibrosis Service.

Do I have to take part?

No. Taking part in this project is entirely voluntary and it will not affect your treatment should you choose not to. You also have the right to withdraw from the project at any time during the study. If you withdraw, any information we have collected from you will be destroyed.

What will happen to me if I do decide to take part?

You will be provided with some information about a patient decision aid tool which has been used in healthcare services in Australia to support people in making decisions around lung transplantation in CF. You will then be asked to take part in an interview about your experiences of support in making this decision and your views on the proposed introduction of a patient decision aid tool into the service.

The interview is estimated to last around 1 hour. It can be held at Bristol Children's Hospital, the University of Bath or within your own home. It will be conducted by Rachel Phillips (Clinical Psychologist in training, Bath University) who is the named researcher on this project. The interviews will need to be audio-recorded so that they can be listened back to afterwards.

What are the benefits of taking part?

We cannot promise that the project will have any direct benefit for you. However, we hope that the information that we get from this project will allow us to develop the service with the aim of helping people to feel better supported in making decisions surrounding whether to have a lung transplant.

What are the potential risks of taking part?

We recognise that the decision to have a lung transplant is an extremely difficult one for those with CF and their significant others and it is possible that talking about the topic may be distressing for some. If you do find that you feel distressed during the course of the project, support is available from the Clinical Psychologists at Bristol Adult Cystic Fibrosis service whose contact details will be made available to you. You will also be provided with other support options that are available to you should you feel you need them.

What happens with my information?

All of the information that we collect is kept confidential. Each person who takes part in the study will be assigned an anonymous participant number and personal details such as names and addresses will not be recorded or included in any written reports. Electronic reports will be kept on password protected computers. Audio recordings made during the interviews will be stored in a locked cabinet. They will be transcribed anonymously and will be deleted at the end of the project.

What if there is a problem?

If you have any concerns or wish to complain about any aspect of this project, you should initially contact the researcher, Rachel Phillips, who will do her best to address your concerns. Her contact details are provided at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting, the University of Bath Secretary Mark Humphriss on 01225 286212 or universitysec@bath.ac.uk. The University of Bath, as Sponsor of the study, has indemnity (insurance) arrangements in place. Every care will be taken to ensure your wellbeing during the course of this project.

What will happen to the findings of the project?

The findings will help shape new service developments in Bristol Adult Cystic Fibrosis Service and may lead to further projects in the area. They will be written into a report which will be presented at a conference and may also be submitted for publication in a journal which would be available to a large amount of people. The write up will be confidential and you will not be identifiable.

For more information, please contact the researcher:

Rachel Phillips
Clinical Psychologist in training
Department of Psychology
University of Bath
Claverton Down
BA2 7AY
rp543@bath.ac.uk
07740105789

The project is supervised by Dr Samantha Phillips (Clinical Psychologist, Bristol Adult and Paediatric Cystic Fibrosis Service; Samantha.Phillips2@UHBristol.nhs.uk) and Dr Elizabeth Marks (Clinical Tutor, University of Bath; E.Marks@bath.ac.uk).

Thank you for taking the time to read this information sheet.

Appendix K: Service Improvement Project Patient Information Sheet (Clinician)

Evaluating the need for a lung transplantation decision aid tool in an NHS Cystic Fibrosis (CF) service

We would like to invite you to take part in our service improvement project. Please take your time to read this information sheet before you make a decision.

What is the purpose of the project?

The project is a service development project which aims to evaluate the support people with CF and their significant others receive from Bristol Adult Cystic Fibrosis Service when they are considering whether to have a lung transplant, and to explore whether the introduction of a patient decision aid tool would improve this. Patient decision aid tools are specially designed information resources that help individuals make difficult decisions about their health and treatment options.

Why have I been invited?

You have been invited to take part because you are a member of staff working within Bristol Adult Cystic Fibrosis Service.

Do I have to take part?

No. Taking part in this project is entirely voluntary. You also have the right to withdraw from the project at any time during the study. If you do choose to withdraw, any information we have collected from you will be destroyed.

What will happen to me if I do decide to take part?

You will be given a short presentation about a patient decision aid tool which has been used in healthcare services in Australia to support people in making decisions around lung transplantation in CF. You will then be asked to take part in a focus group where you can share your experiences of supporting people with this decision in the CF service in the past. You can also share your views on the proposed introduction of a patient decision aid tool into the service.

The focus group is estimated to last around 1 hour and will be held at Bristol Children's Hospital at a mutually convenient time to be agreed. It will be conducted by Rachel Phillips (Clinical Psychologist in training, Bath University) who is the named researcher on this project. The focus group will need to be audio-recorded for transcription purposes. Transcriptions will be anonymised.

What are the potential risks and benefits of taking part?

We cannot promise that the project will have any direct benefit for you. However, we hope that the information that we get from this project will allow us to ensure that people with CF and their families feel best supported in making decisions surrounding whether to have a lung transplant.

We hope that participation in this study will not impact on your wellbeing. However, we recognise that the decision to have a lung transplant can be extremely difficult for people

with CF and their families, and for some professionals having these discussions with patients can be distressing. Should you become distressed as a result of the discussions in this project, emotional support is available to you.

What happens with my information?

All of the information that we collect is kept confidential. Each person who takes part in the study will be assigned an anonymous participant number and personal details will not be recorded or included in any written reports. Electronic reports will be kept on password protected computers. Audio recordings made during the focus group will be stored in a locked cabinet and will be deleted at the end of the project.

What if there is a problem?

If you have any concerns or wish to complain about any aspect of this project, you should initially contact the researcher, Rachel Phillips, who will do her best to address your concerns. Her contact details are provided at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting, the University of Bath Secretary Mark Humphriss on 01225 286212 or universitysec@bath.ac.uk. The University of Bath, as Sponsor of the study, has indemnity (insurance) arrangements in place. Every care will be taken to ensure your wellbeing during the course of this project.

What will happen to the findings of the project?

The findings will help shape new service developments in Bristol Adult Cystic Fibrosis Service and may lead to further projects in the area. They will also be presented at a conference and may also be submitted for publication in a journal. The write up will be confidential and you will not be identifiable.

For more information, please contact the researcher:

Rachel Phillips
Clinical Psychologist in training
Department of Psychology
University of Bath
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BA2 7AY
rp543@bath.ac.uk
07740105789

The project is supervised by Dr Samantha Phillips (Clinical Psychologist, Bristol Adult and Paediatric Cystic Fibrosis Service; Samantha.Phillips2@UHBristol.nhs.uk) and Dr Elizabeth Marks (Clinical Tutor, University of Bath; E.Marks@bath.ac.uk).

Thank you for taking the time to read this information sheet.

Appendix L: Service Improvement Project Consent Form

UNIVERSITY OF BATH

Version 1, 22.10.15

Centre Number:

Study Number:

Patient Identification Number for this trial:

CONSENT FORM

Title of Project: Evaluating the need for a lung transplantation decision aid tool in an NHS Cystic Fibrosis (CF) service

Name of Researcher: Rachel Phillips (Clinical Psychologist in training)

Please initial box

1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I agree for the researcher (Rachel Phillips) and her supervisors to have access to the information produced from my responses for the purposes of this study ☐
4. I agree to be audio-recorded and understand that the recording will be deleted at the end of the study ☐
5. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file.

Appendix M: Journal of Cystic Fibrosis Author Guidelines

Journal of Cystic Fibrosis publishes original scientific articles, editorials, case reports, short communications and other information relevant to cystic fibrosis and is published six times a year. Papers are accepted on the understanding that they have not been published, and are not being considered for publication elsewhere and are subject to editorial revision.

Original articles Original research papers should contain no more than 3,000 words plus no more than 5 figures or tables in total and 30 references. The abstract should consist of 4 paragraphs, labelled Background, Methods, Results, and Conclusions.

Review articles Review papers should be authoritative, well-referenced reviews of a relevant subject and should not contain more than 5,000 words and 30 references with no more than 6 figures or tables.

Letters Headings should not be used in a letter; no abstract or keywords are required. The text should be no more than 800 words; there should be a maximum of 5 references and 1 table or figure may be included.

Correspondence Short articles relating to papers recently published in the Journal, or containing brief reports of unusual or preliminary findings. Maximum length 400 words, 1 table or figure and a maximum of 10 references.

Editorials These tend to be invited papers but unsolicited editorials are welcome. There are no abstract, keywords or section headings.

Short Communications 1,200 words plus no more than 3 figures or tables in total and 20 references.

Case Reports These must be carefully documented and must be of importance because they illustrate or describe unusual features or have important therapeutic implications. Maximum length 1,200 words, no more than a page and a half in length and a maximum of 1 table or figure. Case reports do not require a structured abstract and should include no more than 5 references.

Ensure that the following items are present:

One author has been designated as the corresponding author with contact details:

• E-mail address

• Full postal address

All necessary files have been uploaded:

Manuscript:

• Include keywords

• All figures (include relevant captions)

• All tables (including titles, description, footnotes)

• Ensure all figure and table citations in the text match the files provided

• Indicate clearly if color should be used for any figures in print

Graphical Abstracts / Highlights files (where applicable)

Supplemental files (where applicable)

Further considerations

• Manuscript has been 'spell checked' and 'grammar checked'

• All references mentioned in the Reference List are cited in the text, and vice versa

• Permission has been obtained for use of copyrighted material from other sources (including the Internet)

• Relevant declarations of interest have been made

• Journal policies detailed in this guide have been reviewed

• Referee suggestions and contact details provided, based on journal requirements

Ethics in publishing

Work on human beings that is submitted to Respiratory Medicine should comply with the principles laid down in the Declaration of Helsinki; Recommendations guiding physicians in biomedical research involving human subjects. Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983, and the 41st World Medical Assembly, Hong Kong, September 1989. The manuscript should contain a statement that the work has been approved by the appropriate ethical committees related to the institution(s) in which it was performed and that subjects gave informed consent to the work. Studies involving experiments with animals must state that their care was in accordance with institution guidelines. Patients' and volunteers'

names, initials, and hospital numbers should not be used.

Declaration of interest

All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. If there are no conflicts of interest then please state this: 'Conflicts of interest: none'.

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All authors should have made substantial contributions to all of the following: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content, (3) final approval of the version to be submitted.

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Subscription

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• No open access publication fee payable by authors.

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Please write your text in good English (American or British usage is accepted, but not a mixture of these).

Informed consent and patient details

Studies on patients or volunteers require ethics committee approval and informed consent, which should be documented in the paper. Appropriate consents, permissions and releases must be obtained where an author wishes to include case details or other personal information or images of patients and any other individuals in an Elsevier publication. Written consents must be retained by the author and copies of the consents or evidence that such consents have been obtained must be provided to Elsevier on request. For more information, please review the Elsevier Policy on the Use of Images or Personal Information of Patients or other Individuals. Unless you have written permission from the patient (or, where applicable, the next of kin), the personal details of any patient included in any part of the article and in any supplementary materials (including all illustrations and videos) must be removed before submission.

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Our online submission system guides you stepwise through the process of entering your article details and uploading your files. The system converts your article files to a single PDF file used in the peer-review process. Editable files (e.g., Word, LaTeX) are required

to typeset your article for final publication. All correspondence, including notification of the Editor's decision and requests for revision, is sent by e-mail.

NEW SUBMISSIONS

Submission to this journal proceeds totally online and you will be guided stepwise through the creation and uploading of your files. The system automatically converts your files to a single PDF file, which is used in the peer-review process.

References

There are no strict requirements on reference formatting at submission. References can be in any style or format as long as the style is consistent. Where applicable, author(s) name(s), journal title/book title, chapter title/article title, year of publication, volume number/book chapter and the pagination must be present. Use of DOI is highly encouraged. The reference style used by the journal will be applied to the accepted article by Elsevier at the proof stage. Note that missing data will be highlighted at proof stage for the author to correct.

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There are no strict formatting requirements but all manuscripts must contain the essential elements needed to convey your manuscript, for example Abstract, Keywords, Introduction, Materials and Methods, Results, Conclusions, Artwork and Tables with Captions.

If your article includes any Videos and/or other Supplementary material, this should be included in your initial submission for peer review purposes.
Divide the article into clearly defined sections.

Figures and tables embedded in text

Please ensure the figures and the tables included in the single file are placed next to the relevant text in the manuscript, rather than at the bottom or the top of the file. The corresponding caption should be placed directly below the figure or table.

Cover letter

Corresponding authors must provide a cover letter which includes statements answering the following questions:

•Has the work been seen and approved by all co-authors?

•How is the work clinically relevant, and how does it add to existing research?
•Have papers closely related to the submitted manuscript been published or submitted for publication elsewhere? If so please provide details.
Failure to provide a cover letter addressing each of the questions above will result in the paper being returned to the author. The cover letter must be uploaded as a separate submission item.

REVISED SUBMISSIONS

Use of word processing software

Regardless of the file format of the original submission, at revision you must provide us with an editable file of the entire article. Keep the layout of the text as simple as possible. Most formatting codes will be removed and replaced on processing the article. The electronic text should be prepared in a way very similar to that of conventional manuscripts.

To avoid unnecessary errors you are strongly advised to use the 'spell-check' and 'grammar-check' functions of your word processor.

Subdivision - numbered sections

Divide your article into clearly defined and numbered sections. Subsections should be numbered 1.1 (then 1.1.1, 1.1.2, ...), 1.2, etc. (the abstract is not included in section numbering). Use this numbering also for internal cross-referencing: do not just refer to 'the text'. Any subsection may be given a brief heading. Each heading should appear on its own separate line.

Essential title page information

• ***Title.*** Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.
• ***Author names and affiliations.*** Please clearly indicate the given name(s) and family name(s) of each author and check that all names are accurately spelled. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lower-case superscript letter immediately after the author's name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name and, if available, the e-mail address of each author.
• ***Corresponding author.*** Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication. **Ensure that the e-mail address is given**

and that contact details are kept up to date by the corresponding author.

• ***Present/permanent address.*** If an author has moved since the work described in the article was done, or was visiting at the time, a 'Present address' (or 'Permanent address') may be indicated as a footnote to that author's name. The address at which the author actually did the work must be retained as the main, affiliation address. Superscript Arabic numerals are used for such footnotes.

Avoid use of extraneous words such as "study" and "investigation". The title should be given in capital letters (not exceeding 100 letters), and a running title (not exceeding 50 letters) should also be provided.

If data from the manuscript have been presented at a meeting, list the full name, date and location of the meeting and reference any previous abstracts in the bibliography.

Abstracts

An abstract of your manuscript, summarizing the content, should be provided. A maximum of 150 words, should be written in a structured manner (for original articles only) since this will be the only part of the article studied by some readers. In original articles, the Abstract should consist of 4 paragraphs, labelled Background, Methods, Results, and Conclusions. They should briefly describe the problem being addressed in the study, how the study was performed and which measurements were carried out, the most relevant results, and what the authors conclude from the results.

Keywords

A list of three to six keywords should be supplied: full instructions are provided when submitting the article online

Abbreviations

Define abbreviations that are not standard in this field in a footnote to be placed on the first page of the article. Such abbreviations that are unavoidable in the abstract must be defined at their first mention there, as well as in the footnote. Ensure consistency of abbreviations throughout the article.

Acknowledgements

Collate acknowledgements in a separate section at the end of the article before the references and do not, therefore, include them on the title page, as a footnote to the title or

otherwise. List here those individuals who provided help during the research (e.g., providing language help, writing assistance or proof reading the article, etc.).

Footnotes

Footnotes should be used sparingly. Number them consecutively throughout the article. Many word processors build footnotes into the text, and this feature may be used. Should this not be the case, indicate the position of footnotes in the text and present the footnotes themselves separately at the end of the article.

Artwork

Electronic artwork

General points

• Make sure you use uniform lettering and sizing of your original artwork.
• Preferred fonts: Arial (or Helvetica), Times New Roman (or Times), Symbol, Courier.
• Number the illustrations according to their sequence in the text.
• Use a logical naming convention for your artwork files.
• Indicate per figure if it is a single, 1.5 or 2-column fitting image.
• For Word submissions only, you may still provide figures and their captions, and tables within a single file at the revision stage.
• Please note that individual figure files larger than 10 MB must be provided in separate source files.

Formats

Regardless of the application used, when your electronic artwork is finalized, please 'save as' or convert the images to one of the following formats (note the resolution requirements for line drawings, halftones, and line/halftone combinations given below):
EPS (or PDF): Vector drawings. Embed the font or save the text as 'graphics'.
TIFF (or JPG): Color or grayscale photographs (halftones): always use a minimum of 300 dpi.
TIFF (or JPG): Bitmapped line drawings: use a minimum of 1000 dpi.
TIFF (or JPG): Combinations bitmapped line/half-tone (color or grayscale): a minimum of 500 dpi is required.

Please do not:

• Supply files that are optimized for screen use (e.g., GIF, BMP, PICT, WPG); the resolution is too low.

• Supply files that are too low in resolution.
• Submit graphics that are disproportionately large for the content.

Color artwork

Please make sure that artwork files are in an acceptable format (TIFF (or JPEG), EPS (or PDF), or MS Office files) and with the correct resolution. If, together with your accepted article, you submit usable color figures then Elsevier will ensure, at no additional charge, that these figures will appear in color online (e.g., ScienceDirect and other sites) regardless of whether or not these illustrations are reproduced in color in the printed version. **For color reproduction in print, you will receive information regarding the costs from Elsevier after receipt of your accepted article**. Please indicate your preference for color: in print or online only.

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Ensure that each illustration has a caption. A caption should comprise a brief title (**not** on the figure itself) and a description of the illustration. Keep text in the illustrations themselves to a minimum but explain all symbols and abbreviations used.

Tables

Please submit tables as editable text and not as images. Tables can be placed either next to the relevant text in the article, or on separate page(s) at the end. Number tables consecutively in accordance with their appearance in the text and place any table notes below the table body. Be sparing in the use of tables and ensure that the data presented in them do not duplicate results described elsewhere in the article. Please avoid using vertical rules and shading in table cells.

References

Manuscripts should use the Vancouver style for references.

Citation in text

Please ensure that every reference cited in the text is also present in the reference list (and vice versa). Any references cited in the abstract must be given in full. Unpublished results and personal communications are not recommended in the reference list, but may be mentioned in the text. If these references are included in the reference list they should follow the standard reference style of the journal and should include a substitution of the publication date with either 'Unpublished results' or 'Personal communication'. Citation of

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Reference links

Increased discoverability of research and high quality peer review are ensured by online links to the sources cited. In order to allow us to create links to abstracting and indexing services, such as Scopus, CrossRef and PubMed, please ensure that data provided in the references are correct. Please note that incorrect surnames, journal/book titles, publication year and pagination may prevent link creation. When copying references, please be careful as they may already contain errors. Use of the DOI is encouraged.

A DOI can be used to cite and link to electronic articles where an article is in-press and full citation details are not yet known, but the article is available online. A DOI is guaranteed never to change, so you can use it as a permanent link to any electronic article. An example of a citation using DOI for an article not yet in an issue is: VanDecar J.C., Russo R.M., James D.E., Ambeh W.B., Franke M. (2003). Aseismic continuation of the Lesser Antilles slab beneath northeastern Venezuela. Journal of Geophysical Research, https://doi.org/10.1029/2001JB000884. Please note the format of such citations should be in the same style as all other references in the paper.

Web references

As a minimum, the full URL should be given and the date when the reference was last accessed. Any further information, if known (DOI, author names, dates, reference to a source publication, etc.), should also be given. Web references can be listed separately (e.g., after the reference list) under a different heading if desired, or can be included in the reference list.

References in a special issue

Please ensure that the words 'this issue' are added to any references in the list (and any citations in the text) to other articles in the same Special Issue.

Reference formatting

There are no strict requirements on reference formatting at submission. References can be in any style or format as long as the style is consistent. Where applicable, author(s) name(s), journal title/book title, chapter title/article title, year of publication, volume number/book chapter and the pagination must be present. Use of DOI is highly encouraged. The reference style used by the journal will be applied to the accepted article by Elsevier at the proof stage. Note that missing data will be highlighted at proof stage for

the author to correct. If you do wish to format the references yourself they should be arranged according to the following examples:

Reference style

Text: Indicate references by number(s) in square brackets in line with the text. The actual authors can be referred to, but the reference number(s) must always be given.

List: Number the references (numbers in square brackets) in the list in the order in which they appear in the text.

Examples:

Reference to a journal publication:

[1] Van der Geer J, Hanraads JAJ, Lupton RA. The art of writing a scientific article. J Sci Commun 2010;163:51–9.

Reference to a book:

[2] Strunk Jr W, White EB. The elements of style. 4th ed. New York: Longman; 2000.

Reference to a chapter in an edited book:

[3] Mettam GR, Adams LB. How to prepare an electronic version of your article. In: Jones BS, Smith RZ, editors. Introduction to the electronic age, New York: E-Publishing Inc; 2009, p. 281–304.

Reference to a website:

[4] Cancer Research UK. Cancer statistics reports for the UK, http://www.cancerresearchuk.org/aboutcancer/statistics/cancerstatsreport/; 2003 [accessed 13.03.03].

Reference to a dataset:

[dataset] [5] Oguro M, Imahiro S, Saito S, Nakashizuka T. Mortality data for Japanese oak wilt disease and surrounding forest compositions, Mendeley Data, v1; 2015. https://doi.org/10.17632/xwj98nb39r.1.

Note shortened form for last page number. e.g., 51–9, and that for more than 6 authors the first 6 should be listed followed by 'et al.' For further details you are referred to 'Uniform Requirements for Manuscripts submitted to Biomedical Journals' (J Am Med Assoc 1997;277:927–34) (see also Samples of Formatted References).

Video

Elsevier accepts video material and animation sequences to support and enhance your scientific research. Authors who have video or animation files that they wish to submit with their article are strongly encouraged to include links to these within the body of the article. This can be done in the same way as a figure or table by referring to the video or

animation content and noting in the body text where it should be placed. All submitted files should be properly labeled so that they directly relate to the video file's content. In order to ensure that your video or animation material is directly usable, please provide the files in one of our recommended file formats with a preferred maximum size of 150 MB. Video and animation files supplied will be published online in the electronic version of your article in Elsevier Web products, including ScienceDirect. Please supply 'stills' with your files: you can choose any frame from the video or animation or make a separate image. These will be used instead of standard icons and will personalize the link to your video data. For more detailed instructions please visit our video instruction pages. Note: since video and animation cannot be embedded in the print version of the journal, please provide text for both the electronic and the print version for the portions of the article that refer to this content.

Supplementary material

Supplementary material such as applications, images and sound clips, can be published with your article to enhance it. Submitted supplementary items are published exactly as they are received (Excel or PowerPoint files will appear as such online). Please submit your material together with the article and supply a concise, descriptive caption for each supplementary file. If you wish to make changes to supplementary material during any stage of the process, please make sure to provide an updated file. Do not annotate any corrections on a previous version. Please switch off the 'Track Changes' option in Microsoft Office files as these will appear in the published version.

Additional Information

Authors should use the 'Track Changes' option when revising their manuscripts, so that any changes made to the original submission are easily visible to the Editors. Those revised manuscripts upon which the changes are not clear may be returned to the author. Specific comments made in the Author Comments in response to referees' comments must be organised clearly. For example, use the same numbering system as the referee, or use 2 columns of which one states the comment and the other the response.

Appendix N: HRA Approval for Main Research Project

NHS
Health Research Authority

Miss Rachel Phillips
Clinical Psychologist in Training
Taunton and Somerset NHS Trust
University of Bath, Department of Clinical Psychology
Claverton Down
Bath
BA2 7AY

Email: hra.approval@nhs.net

18 November 2016

Dear Miss Phillips

Letter of HRA Approval

Study title:	**The Role of Health Anxiety in Mild Cognitive Impairment**
IRAS project ID:	**200877**
Protocol number:	**N/A**
REC reference:	**16/SC/0557**
Sponsor	**University of Bath**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the ***After Ethical Review*** document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application

IRAS project ID	200877

procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **200877**. Please quote this on all correspondence.

Yours sincerely

Simon Connolly
Senior Assessor

Email: hra.approval@nhs.net

Appendix O: Main Research Project Patient Information Sheet – MCI Group

Participant Information Sheet – MCI Group

17.06.16 (version 2)

The Role of Health Anxiety in Mild Cognitive Impairment

We would like to invite you to take part in our research project. Please take your time to read this information sheet and feel free to talk it through with others before you make a decision should you so wish.

What is the purpose of the project?

The project aims to explore the relationship between receiving a diagnosis of a Mild Cognitive Impairment and how worried people feel about their health (health anxiety). Mild Cognitive Impairment (MCI) is a term used to describe the experience of having difficulties with your thinking (e.g. memory problems) that are detected on tests but do not meet the criteria for a dementia. Some people who are told that they have an MCI go on to develop a dementia whilst others do not. This can make MCI a very uncertain diagnosis to receive and we are interested in whether this uncertainty makes people more or less worried about their health.

In order to understand if having an MCI specifically influences peoples' worries about their health, we will also be looking at how worried people who do not have MCI feel about their health. This will allow us to compare people with and without MCI.

Why have I been invited?

You have been invited to take part because you are an adult over the age of 50 years old and have been diagnosed with MCI following an assessment from an NHS memory service.

Do I have to take part?

No. Taking part in this project is entirely voluntary. You also have the right to withdraw from the project at any time during the study. If you withdraw, any information we have collected from you will be destroyed.

What will happen to me if I do decide to take part?

You will be asked to complete four short questionnaires about your overall mood, how worried you feel about your health and your views on MCI. You will then be asked to take part in a short interview with the researcher who will ask you questions about your perception of your quality of life. Finally you will be asked to complete two short tests of your thinking and rate your performance on these tests afterwards.

We will also ask you to identify a family member/spouse/friend who knows you well to complete a short questionnaire about how they feel you manage day to day tasks (e.g. household chores, eating and drinking, cooking etc.). If you choose to bring someone with you to the appointment, we can ask them to

complete this at the same time. Alternatively, it can be completed with someone on the phone at a later date.
Taking part in this study is estimated to last around 1 – 2 hours. We will only need to meet with you once. We can meet at your local memory service, GP surgery (subject to approval), the University of Bath or within your own home. It will be conducted by Rachel Phillips (Clinical Psychologist in training, Bath University) who is the named researcher on this project.

What are the benefits of taking part?
We cannot promise that the project will have any direct benefit for you. However, we hope that the information that we get from this project will allow us to better understand the experience of and potential consequences of receiving a diagnosis of MCI. We hope that these results will better inform professionals working with people who are concerned about their thinking in how they best communicate the results of their assessments to individuals. We also hope that it will highlight potential support needs of people with MCI beyond what it is currently provided.

What are the potential risks of taking part?
Although we do not anticipate participating in the study to be a distressing process, we so recognise that the topics covered by this project can be quite sensitive ones and so support is available should you feel concerned following your participation. This research is supervised by two Clinical Psychologists whose contact details are at the end of this information sheet if you wished to discuss any concerns you may have with them. You can also discuss any concerns you have directly with the researcher. In addition you will be provided with contact details of third party organisations that would also be able to offer support and guidance.

What happens with my information?
All of the information that we collect is kept confidential. Each person who takes part in the study will be assigned an anonymous participant number and personal details such as names and addresses will not be recorded or included in any written reports. Electronic reports will be kept on password protected computers. Paper records will be kept in a locked cabinet which is only accessible by the researcher and the research supervisors.

We are interested in exploring the possibility of completing a follow up study at a later date. As such we would like to securely store data from this study at the University of Bath for a period of up to 5 years to allow for the potential of a follow up study to be pursued. In the event of a follow up study taking place, you will be contacted directly to provide consent prior to its start. Should you decide that you do not want us to store your data for this purpose, this will not affect your ability to take part in the current study.

What if there is a problem?
If you have any concerns or wish to complain about any aspect of this project, you should initially contact the researcher, Rachel Phillips, who will do her best to address your concerns. Her contact details are provided at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting, the University of Bath Secretary Mark Humphriss on 01225 286212 or universitysec@bath.ac.uk. The University of Bath, as Sponsor of the study, has indemnity (insurance) arrangements in place. Every care will be taken to ensure your wellbeing during the course of this project.

What will happen to the findings of the project?
The findings will help inform the professional literature around the experience of receiving a diagnosis of MCI and may lead to further projects in the area. We also hope it will inform services as to how they may best shape their clinical practice. The results will be written up into a report to be submitted for publication in a professional journal which would be available to a large amount of people. The write up will be confidential and you will not be identifiable. If you want to receive a copy of the results, please let the researcher know who can send them to you on completion.

For more information, please contact the researcher:
Rachel Phillips
Clinical Psychologist in training
Department of Psychology
University of Bath
Claverton Down
BA2 7AY
rp543@bath.ac.uk
07740105789

The project is supervised by Professor Paul Salkovskis (Programme Director and Clinical Psychologist, The University of Bath; p.m.salkovskis@bath.ac.uk) and Dr Orazio Giuffrida (Clinical Psychologist, Herefordshire Memory Service; orazio.giuffrida@nhs.net).

Thank you for taking the time to read this information sheet.

Appendix P: Main Research Project Patient Information Sheet – Healthy Controls

Participant Information Sheet – Control Group

17.06.16 (version 1)

The Role of Health Anxiety in Mild Cognitive Impairment

We would like to invite you to take part in our research project. Please take your time to read this information sheet and feel free to talk it through with others before you make a decision should you so wish.

What is the purpose of the project?

The project aims to explore the relationship between receiving a diagnosis of a Mild Cognitive Impairment and how worried people feel about their health (health anxiety). Mild Cognitive Impairment (MCI) is a term used to describe the experience of having difficulties with your thinking (e.g. memory problems) that are detected on tests but do not meet the criteria for a dementia. Some people who are told that they have an MCI go on to develop a dementia whilst others do not. This can make MCI a very uncertain diagnosis to receive and we are interested in whether this uncertainty makes people more or less worried about their health.

In order to understand if having an MCI specifically influences peoples' worries about their health, we are also interested in looking at how worried people who do not have MCI feel about their health. This will allow us to compare people with and without MCI.

Why have I been invited?

You have been invited to take part because you are an adult over the age of 50 years old who does not have any diagnosed problems with their thinking (i.e. you do not have MCI, a dementia or any other neurological problem).

Do I have to take part?

No. Taking part in this project is entirely voluntary. You also have the right to withdraw from the project at any time during the study. If you withdraw, any information we have collected from you will be destroyed.

What will happen to me if I do decide to take part?

Firstly, you will be asked to complete a short screening task to ensure that you do not have any difficulties with your thinking. This screening task is made up of a number of brief pen and paper tests that look at different areas of your thinking, such as memory, attention and language. Scores of 26 or above (maximum score of 30) on the screening task will mean that people are eligible to take part in the remainder of the study, Scores falling below 26 would mean that you could not take part in the rest of the research. Please see the 'What are the risks of taking part?' section below for further details of what happens in the event that your score falls below 26.

Following the screening task, you will be asked to complete four short questionnaires about your overall mood, how worried you feel about your health

and your views on illness. You will then be asked to take part in a short interview with the researcher who will ask you questions about your perception of your quality of life. Finally you will be asked to complete two short tests of your thinking and rate your performance on these tests afterwards.

We will also ask you to identify a family member/spouse/friend who knows you well to complete a short questionnaire about how they feel you manage day to day tasks (e.g. household chores, eating and drinking, cooking etc.). If you choose to bring someone with you to the appointment, we can ask them to complete this at the same time. Alternatively, it can be completed with someone on the phone at a later date.

Taking part in this study is estimated to last around 1 – 2 hours. We will only need to meet with you once. We can meet at your GP surgery (subject to approval), the University of Bath or within your own home. It will be conducted by Rachel Phillips (Clinical Psychologist in training, Bath University) who is the named researcher on this project.

What are the benefits of taking part?
We cannot promise that the project will have any direct benefit for you. However, we hope that the information that we get from this project will allow us to better understand the experience of and potential consequences of receiving a diagnosis of MCI. We hope that these results will better inform professionals working with people who are concerned about their thinking in how they best communicate the results of their assessments with individuals. We also hope that it will highlight potential support needs of people with MCI beyond what it is currently provided.

What are the potential risks of taking part?
Although we do not anticipate this to be a frequent outcome, it is possible that the screening test may suggest that you have some difficulties with your thinking. If this is indicated, then we would ask for your consent to send a copy of our tests with an accompanying letter to your GP to explain your role in the research and ask them to arrange a time to meet with you to discuss these results further. They would then be able to discuss with you the possibility of a referral to your local memory clinic for further investigation into this if you wanted them to. If you did not want us to contact your GP with this information then we would ask for your consent to give you a follow up telephone call in 1-2 weeks time to check whether you would like any further support.

This research is supervised by two Clinical Psychologists whose contact details are at the end of this information sheet if you wished to discuss any concerns you may have with them. You can also discuss any concerns you have directly with the researcher. In addition you will be provided with contact details of third party organisations that would also be able to offer support and guidance. These resources could also be used should you find the process of the research distressing. Although we do not anticipate this to be a distressing process, we recognise that the topics covered by this project can be quite sensitive ones and so support is available should you feel concerned following your participation.

What happens with my information?
All of the information that we collect is kept confidential. Each person who takes part in the study will be assigned an anonymous participant number and personal details such as names and addresses will not be recorded or included in any

written reports. Electronic reports will be kept on password protected computers. Paper records will be kept in a locked cabinet which is only accessible by the researcher and the research supervisors.

We are interested in exploring the possibility of completing a follow up study at a later date. As such we would like to securely store data from this study at the University of Bath for a period of up to 5 years to allow for the potential of a follow up study to be pursued. In the event of a follow up study taking place, you will be contacted directly to provide consent prior to its start. Should you decide that you do not want us to store your data for this purpose, this will not affect your ability to take part in the current study.

What if there is a problem?
If you have any concerns or wish to complain about any aspect of this project, you should initially contact the researcher, Rachel Phillips, who will do her best to address your concerns. Her contact details are provided at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting, the University of Bath Secretary Mark Humphriss on 01225 286212 or universitysec@bath.ac.uk. The University of Bath, as Sponsor of the study, has indemnity (insurance) arrangements in place. Every care will be taken to ensure your wellbeing during the course of this project.

What will happen to the findings of the project?
The findings will help inform the professional literature around the experience of receiving a diagnosis of MCI and may lead to further projects in the area. We also hope it will inform services as to how they may best shape their clinical practice. The results will be written up into a report to be submitted for publication in a professional journal which would be available to a large amount of people. The write up will be confidential and you will not be identifiable. If you want to receive a copy of the results, please let the researcher know who can send them to you on completion.

For more information, please contact the researcher:
Rachel Phillips
Clinical Psychologist in training
Department of Psychology
University of Bath
Claverton Down
BA2 7AY
rp543@bath.ac.uk
07740105789

The project is supervised by Professor Paul Salkovskis (Programme Director and Clinical Psychologist, The University of Bath; p.m.salkovskis@bath.ac.uk) and Dr Orazio Giuffrida (Clinical Psychologist, Herefordshire Memory Service; orazio.giuffrida@nhs.net).

Thank you for taking the time to read this information sheet

Appendix Q: Main Research Project Consent Form

Version 1, 23.04.16

Centre Number:
Study Number:
Patient Identification Number for this trial:

CONSENT FORM

Title of Project: The role of Health Anxiety in Mild Cognitive Impairment
Name of Researcher: Rachel Phillips (Clinical Psychologist in training)

Please initial box

1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I agree for the researcher (Rachel Phillips) and her supervisors to have access to the information produced from my responses for the purposes of this study ☐

4. I agree for the researcher (Rachel Phillips) to contact my spouse/partner/relative/close friend (please delete as appropriate) to ask them to complete a questionnaire giving their views on my day to day functioning. I understand that their responses will be used for the purpose of this study. ☐

5. I agree to take part in the above study. ☐

6. I agree to my data being securely stored by the University of Bath for a period of up to 5 years to allow for the potential of a follow up study to be pursued. In the event of this study taking place, I understand that I will be contacted directly to provide consent prior to its start. I understand that should I choose to decline for my details to be stored, this will not affect my ability to partake in the current study. ☐

_____	_____	_____
Name of Participant	Date	Signature

_____	_____	_____
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file.

Appendix R: Geriatric Depression Scale (GDS)

Geriatric Depression Scale (Short Form)
Self-Rated Version

Patient's Name: _____ Date: _____

***Instructions*: Choose the best answer for how you felt over the past week.**

No.	Question	Answer	Score
1.	Are you basically satisfied with your life?	YES / NO	
2.	Have you dropped many of your activities and interests?	YES / NO	
3.	Do you feel that your life is empty?	YES / NO	
4.	Do you often get bored?	YES / NO	
5.	Are you in good spirits most of the time?	YES / NO	
6.	Are you afraid that something bad is going to happen to you?	YES / NO	
7.	Do you feel happy most of the time?	YES / NO	
8.	Do you often feel helpless?	YES / NO	
9.	Do you prefer to stay at home, rather than going out and doing new things?	YES / NO	
10.	Do you feel you have more problems with memory than most people?	YES / NO	
11.	Do you think it is wonderful to be alive?	YES / NO	
12.	Do you feel pretty worthless the way you are now?	YES / NO	
13.	Do you feel full of energy?	YES / NO	
14.	Do you feel that your situation is hopeless?	YES / NO	
15.	Do you think that most people are better off than you are?	YES / NO	
		TOTAL	

(Sheikh & Yesavage, 1986)

Appendix S: Short-form Health Anxiety Inventory (SHAI)

HAI

Participant number: _____ date: _____

Each question is this section consists of a group of four statements. Please read each group of statements carefully and then select the one which best describes your feelings, over the past six months (or other agreed time period). Identify the statement by ringing the letter next to it, i.e. if you think that statement *a.)* is correct, ring statement *a.)*. It may be that more than one statement applies, in which case, please ring any that are applicable.

1. *a.)* I do not worry about my health.
b.) I occasionally worry about my health.
c.) I spend much of my time worrying about my health.
d.) I spend most of my time worrying about my health.

2. *a.)* I notice aches/pains less than most other people (of my age).
b.) I notice aches/pains as much as most other people (of my age).
c.) I notice aches/pains more than most other people (of my age).
d.) I am aware of aches/pains in my body all the time.

3. *a.)* as a rule I am not aware of bodily sensations or changes.
b.) sometimes I am aware of bodily sensations or changes.
c.) I am often aware of bodily sensations or changes.
d.) I am constantly aware of bodily sensations or changes.

4. *a.)* resisting thoughts of illness is never a problem.
b.) most of the time I can resist thoughts of illness.
c.) I try to resist thoughts of illness but am often unable to do so.
d.) thoughts of illness are so strong that I no longer even try to resist them.

5. *a.)* as a rule I am not afraid that I have a serious illness.
b.) I am sometimes afraid that I have a serious illness.
c.) I am often afraid that I have a serious illness.
d.) I am always afraid that I have a serious illness.

6. *a.)* I do not have images (mental pictures) of myself being ill.
b.) I occasionally have images of myself being ill.
c.) I frequently have images of myself being ill.
d.) I constantly have images of myself being ill.

7. *a.)* I do not have any difficulty taking my mind off thoughts about my health.
b.) I sometimes have difficulty taking my mind off thoughts about my health.
c.) I often have difficulty in taking my mind off thoughts about my health.
d.) Nothing can take my mind off thoughts about my health.

8. *a.)* I am lastingly relieved if my doctor tells me there is nothing wrong.
b.) I am initially relieved but the worries sometimes return later.
c.) I am initially relieved but the worries always return later.
d.) I am not relieved if my doctor tells me there is nothing wrong.

9. *a.)* if I hear about an illness I never think I have it myself.
b.) if I hear about an illness I sometimes think I have it myself.
c.) if I hear about an illness I often think I have it myself.
d.) if I hear about an illness I always think I have it myself.

10. *a.)* if I have a bodily sensation or change I rarely wonder what it means.
b.) if I have a bodily sensation or change I often wonder what it means.
c.) if I have a bodily sensation or change I always wonder what it means.
d.) if I have a bodily sensation or change I must know what it means.

[cont.]

11. a.) I usually feel at very low risk for developing a serious illness.
b.) I usually feel at fairly low risk for developing a serious illness.
c.) I usually feel at moderate risk for developing a serious illness.
d.) I usually feel at high risk for developing a serious illness.

12. *a.)* I never think I have a serious illness.
b.) I sometimes think I have a serious illness.
c.) I often think I have a serious illness.
d.) I usually think that I am seriously ill.

13. *a.)* if I notice an unexplained bodily sensation I don't find it difficult to think about other things.
b.) if I notice an unexplained bodily sensation I sometimes find it difficult to think about other things.
c.) if I notice an unexplained bodily sensation I often find it difficult to think about other things.
d.) if I notice an unexplained bodily sensation I always find it difficult to think about other things.

14. *a.)* my family/friends would say I do not worry enough about my health.
b.) my family/friends would say I have a normal attitude to my health.
c.) my family/friends would say I worry too much about my health.
d.) my family/friends would say I am a hypochondriac.

Appendix T: Illness Perceptions Questionnaire – MCI (IPQ-MCI)

Illness Perceptions Questionnaire – Mild Cognitive Impairment (Adapted Version)

Participant number: _____ **Date:** _____

Part 1

We are interested in your own personal views of how you now see Mild Cognitive Impairment (MCI).

Please indicate how much you agree or disagree with the following statements about MCI by ticking the appropriate box.

MCI is a serious condition

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

MCI has major consequences for my life

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

MCI causes difficulties for those who are close to me

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

MCI does not have much effect on my life

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

MCI makes me feel stigmatised

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

MCI makes me lose my independence

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

MCI strongly affects the way others see or treat me

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

MCI will progress to dementia

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

MCI has serious financial consequences

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

MCI makes me lose my self confidence

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Part 2

We are interested in what you consider may have been the cause of MCI. As people are very different, there is no correct answer for this question.

We are most interested in your own views about the factors that caused MCI rather than what others including doctors or family may have suggested to you.

Below is a list of possible causes for MCI. Please indicate how much you agree or disagree that they were causes for you by ticking the appropriate box.

Stress or worry

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Hereditary, genetic risk factor

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

History of stroke

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

A germ or virus

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Diet or eating habits

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Retirement (e.g. not as active as before)

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Chance or bad luck

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Poor medical care in my past

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Pollution in the environment

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Lack of antioxidants, such as Vitamin C

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

My own behaviour

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

My mental attitude (e.g. thinking about life negatively)

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Family problems or worries caused the MCI

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Overwork

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Chronic illness (e.g. Diabetes, High blood pressure)

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

My emotional state (e.g. feeling down, lonely, anxious, empty)

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Aging

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Obesity

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Alcohol

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Smoking

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Abnormal changes in the brain

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Accident or injury

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Medication side-effects

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

My personality

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Poor immune system

Strongly agree	Agree	Neither agree not disagree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

In the table below, please list in rank-order the three most important factors that you now believe caused YOUR MCI. You may use any of the items from the list above, or you may have additional ideas of your own.

The most important causes for me:-

1. _____

2. _____

3. _____

Appendix U: Quality of Life – AD (QoL-AD)

Quality of Life: AD
(Interview Version for the person with dementia)

Interviewer administer according to standard instructions. Circle responses.				
1. Physical health.	Poor	Fair	Good	Excellent
2. Energy.	Poor	Fair	Good	Excellent
3. Mood.	Poor	Fair	Good	Excellent
4. Living situation.	Poor	Fair	Good	Excellent
5. Memory.	Poor	Fair	Good	Excellent
6. Family.	Poor	Fair	Good	Excellent
7. Marriage.	Poor	Fair	Good	Excellent
8. Friends.	Poor	Fair	Good	Excellent
9. Self as a whole.	Poor	Fair	Good	Excellent
10. Ability to do chores around the house.	Poor	Fair	Good	Excellent
11. Ability to do things for fun.	Poor	Fair	Good	Excellent
12. Money.	Poor	Fair	Good	Excellent
13. Life as a whole.	Poor	Fair	Good	Excellent

Comments:_____

Quality of Life-AD
Instructions for Interviewers

The QOL-AD is administered in interview format to individuals with dementia, following the instructions below. Hand the form to the participant, so that he or she may look at it as you give the following instructions (instructions should closely follow the wording given in bold type):

I want to ask you some questions about your quality of life and have you rate different aspects of your life using one of four words: poor, fair, good, or excellent.

Point to each word (poor, fair, good, and excellent) on the form as you say it.

When you think about your life, there are different aspects, like your physical health, energy, family, money, and others. I'm going to ask you to rate each of these areas. We want to find out how you feel about your current situation in each area.

If you're not sure about what a question means, you can ask me about it. If you have difficulty rating any item, just give it your best guess.

It is usually apparent whether an individual understands the questions, and most individuals who are able to communicate and respond to simple questions can understand the measure. If the participant answers all questions the same, or says something that indicates a lack of understanding, the interviewer is encouraged to clarify the question. However, under no circumstances should the interviewer suggest a specific response. Each of the four possible responses should be presented, and the participant should pick one of the four.

If a participant is unable to choose a response to a particular item or items, this should be noted in the comments. If the participant is unable to comprehend and/or respond to two or more items, the testing may be discontinued, and this should be noted in the comments.

As you read the items listed below, ask the participant to circle her/his response. If the participant has difficulty circling the word, you may ask her/him to point to the word or say the word, and you may circle it for him or her. You should let the participant hold his or her own copy of the measure, and follow along as you read each item.

1. **First of all, how do you feel about your physical health? Would you say it's poor, fair, good, or excellent? Circle whichever word you think best describes your physical health right now.**

2. **How do you feel about your energy level? Do you think it is poor, fair, good, or excellent?** If the participant says that some days are better than others, ask him or her to rate how she/he has been feeling most of the time lately.

3. **How has your mood been lately? Have your spirits been good, or have you been feeling down? Would you rate your mood as poor, fair, good, or excellent?**
4. **How about your living situation? How do you feel about the place you live now? Would you say it's poor, fair, good, or excellent?**

5. **How about your memory? Would you say it is poor, fair, good, or excellent?**

6. **How about your family and your relationship with family members? Would you describe it as poor, fair, good, or excellent?** If the respondent says they have no family, ask about brothers, sisters, children, nieces, nephews.

7. **How do you feel about your marriage? How is your relationship with (spouse's name). Do you feel it's poor, fair, good, or excellent?** Some participants will be single, widowed, or divorced. When this is the case, ask how they feel about the person with whom they have the closest relationship, whether it's a family member or friend. If there is a family caregiver, ask about their relationship with this person. It there is no one appropriate, or the participant is unsure, score the item as missing. If the participant's rating is of their relationship with someone other than their spouse, note this and record the relationship in the comments section.

8. **How would you describe your current relationship with your friends? Would you say it's poor, fair, good, or excellent?** If the respondent answers that they have no friends, or all their friends have died, probe further. **Do you have anyone you enjoy being with besides your family? Would you call that person a friend?** If the respondent still says they have no friends, ask **how do you feel about having no friends—poor, fair, good, or excellent?**

9. **How do you feel about yourself—when you think of your whole self, and all the different things about you, would you say it's poor, fair, good, or excellent?**

10. **How do you feel about your ability to do things like chores around the house or other things you need to do? Would you say it's poor, fair, good, or excellent?**

11. **How about your ability to do things for fun, that you enjoy? Would you say it's poor, fair, good, or excellent?**

12. **How do you feel about your current situation with money, your financial situation? Do you feel it's poor, fair, good, or excellent?** If the respondent hesitates, explain that you don't want to know what their situation is (as in amount of money), just how they feel about it.

13. **How would you describe your life as a whole. When you think about your life as a whole, everything together, how do you feel about your life? Would you say it's poor, fair, good, or excellent?**

SCORING INSTRUCTIONS FOR THE QOL:
Points are assigned to each item as follows: poor=1, fair=2, good=3, excellent=4.
The total score is the sum of all 13 items.

Appendix V: Bristol Activity of Daily Living Scale (BADLs)

Bristol Activities of Daily Living Scale

Bucks, R. S., Ashworth, D. L., Wilcock, G. K., and Siegfried, K. (1996)

Bristol Activities of Daily Living Scale

Name of patient:……

Patient number:

Carer's Name:……

Assessment date: ……/……/…..

Relationship:……...

This questionnaire is designed to reveal the everyday ability of people who have memory difficulties of one form or another.

For each activity (No. 1 - 20), statements a - e refer to a different level of ability.

Thinking of the last 2 weeks, tick the box that represents your relative's/friend's AVERAGE ability. (If in doubt about which box to tick, choose the level of ability which represents their *average* performance over the last 2 Weeks. Tick 'Not applicable' if your relative never did that activity when they were well).

1. PREPARING FOOD		a) Selects and prepares food as required b) Able to prepare food if ingredients set out c) Can prepare food if prompted step by step d) Unable to prepare food even with prompting and supervision e) Not applicable
2. EATING		a) Eats appropriately using correct cutlery b) Eats appropriately if food made manageable and/or uses spoon c) Uses fingers to eat food d) Needs to be fed e) Not applicable
3. PREPARING DRINK		a) Selects and prepares drinks as required b) Can prepare drinks if ingredients left available c) Can prepare drinks if prompted step by step d) Unable to make a drink even with prompting and supervision e) Not applicable

4. DRINKING		a) Drinks appropriately b) Drinks appropriately with aids, beaker/straw etc. c) Does not drink appropriately even with aids but attempts to d) Has to have drinks administered (fed) e) Not applicable
5. DRESSING		a) Selects appropriate clothing and dresses self b) Puts clothes on in wrong order and/or back to front and/or dirty clothing c) Unable to dress self but moves limbs to assist d) Unable to assist and requires total dressing e) Not applicable
6. HYGIENE		a) Washes regularly and independently b) Can wash self if given soap, flannel, towel, etc c) Can wash self if prompted and supervised d) Unable to wash self and needs full assistance e) Not applicable
7. TEETH		a) Cleans own teeth/dentures regularly and independently b) Cleans teeth/dentures if given appropriate items c) Requires some assistance, toothpaste on brush, brush to mouth etc d) Full assistance given e) Not applicable
8. BATH/SHOWER		a) Bathes regularly and independently b) Needs bath to be drawn/shower turned on but washes independently c) Needs supervision and prompting to wash d) Totally dependent, needs full assistance e) Not applicable
9. TOILET/COMMODE		a) Uses toilet appropriately when required b) Needs to be taken to the toilet and given assistance c) Incontinent of urine or faeces d) Incontinent of urine and faeces e) Not applicable
10. TRANSFERS		a) Can get in/out of chair unaided b) Can get into a chair but needs help to get out c) Needs help getting in and out of a chair d) Totally dependent on being put into and lifted from chair e) Not applicable

11. MOBILITY		a) Walks independently b) Walks with assistance ie furniture, arm for support c) Uses aids to mobilise ie frame, sticks etc d) Unable to walk e) Not applicable
12. ORIENTATION – TIME		a) Fully orientated to time/day/date etc b) Unaware of time/day etc but seems unconcerned c) Repeatedly asks the time/day/date d) Mixes up night and day e) Not applicable
13. ORIENTATION – SPACE		a) Fully orientated to surroundings b) Orientated to familiar surroundings only c) Gets lost in home, needs reminding where bathroom is, etc d) Does not recognise home as own and attempts to leave e) Not applicable
14. COMMUNICATION		a) Able to hold appropriate conversation b) Shows understanding and attempts to respond verbally with gestures c) Can make self understood but difficulty understanding others d) Does not respond to, or communicate with others e) Not applicable
15. TELEPHONE		a) Uses telephone appropriately, including obtaining correct number b) Uses telephone if number given verbally/visually or predialled c) Answers telephone but does not make calls d) Unable/unwilling to use telephone at all e) Not applicable
16. HOUSEWORK/ GARDNEING		a) Able to do housework/gardening to previous standard b) Able to do housework/gardening but not to previous standard c) Limited participation with a lot of supervision d) Unwilling/unable to participate in previous activities e) Not applicable

17. SHOPPING		a) Shops to previous standard b) Only able to shop for 1 or 2 items with or without a list c) Unable to shop alone, but participates when accompanied d) Unable to participate in shopping even when accompanied e) Not applicable
18. FINANCES		a) Responsible for own finances at previous level b) Unable to write cheque. Can sign name & recognises money values c) Can sign name but unable to recognise money values d) Unable to sign name or recognise money values e) Not applicable
19. GAMES/HOBBIES		a) Participates in pastimes/activities to previous standard b) Participates but needs instruction/supervision c) Reluctant to join in, very slow needs coaxing d) No longer able or willing to join in e) Not applicable
20. TRANSPORT		a) Able to drive, cycle or use public transport independently b) Unable to drive but uses public transport or bike etc c) Unable to use public transport alone d) Unable/unwilling to use transport even when accompanied e) Not applicable

Self-ratings of performance on tasks

Please rate on the scale below how well you believed you performed on the two tasks that you just completed, when compared to the average person of your age by ticking the appropriate box.

<u>Task 1:</u> Memory test (remembering word pairs)

I believe that compared to the average person of my age, I performed....

Well above average	Above average	Average	Below average	Well below average
☐	☐	☐	☐	☐

<u>Task 2:</u> Picture completion test (what is missing in the pictures)

I believe that compared to the average person of my age, I performed....

Well above average	Above average	Average	Below average	Well below average
☐	☐	☐	☐	☐

We are also interested in how much of a role you believe your diagnosed Mild Cognitive Impairment (MCI) played in your performance today. Please rate on the scale below the degree to which you believe your performance would have changed if you did not have MCI by ticking the appropriate box.

<u>Task 1:</u> Memory test (remembering word pairs)

I believe that if I did not have MCI, my performance would have been....

Significantly higher	Higher	Neither higher nor lower	Lower	Significantly lower
☐	☐	☐	☐	☐

<u>Task 2:</u> Picture completion test (what is missing in the pictures)

I believe that if I did not have MCI, my performance would have been....

Significantly higher	Higher	Neither higher nor lower	Lower	Significantly lower
☐	☐	☐	☐	☐

Appendix X: British Journal of Clinical Psychology Author Guidelines

The British Journal of Clinical Psychology publishes original contributions to scientific knowledge in clinical psychology. This includes descriptive comparisons, as well as studies of the assessment, aetiology and treatment of people with a wide range of psychological problems in all age groups and settings. The level of analysis of studies ranges from biological influences on individual behaviour through to studies of psychological interventions and treatments on individuals, dyads, families and groups, to investigations of the relationships between explicitly social and psychological levels of analysis.

All papers published in The British Journal of Clinical Psychology are eligible for Panel A: Psychology, Psychiatry and Neuroscience in the Research Excellence Framework (REF).

The following types of paper are invited:
• Papers reporting original empirical investigations
• Theoretical papers, provided that these are sufficiently related to the empirical data
• Review articles which need not be exhaustive but which should give an interpretation of the state of the research in a given field and, where appropriate, identify its clinical implications
• Brief reports and comments

1. Circulation
The circulation of the Journal is worldwide. Papers are invited and encouraged from authors throughout the world.

2. Length
The word limit for papers submitted for consideration to BJCP is 5000 words and any papers that are over this word limit will be returned to the authors. The word limit does not include the abstract, reference list, figures, or tables. Appendices however are included in the word limit. The Editors retain discretion to publish papers beyond this length in cases where the clear and concise expression of the scientific content requires greater length. In such a case, the authors should contact the Editors before submission of the paper.

3. Submission and reviewing

All manuscripts must be submitted via Editorial Manager. The Journal operates a policy of anonymous (double blind) peer review. We also operate a triage process in which submissions that are out of scope or otherwise inappropriate will be rejected by the editors without external peer review to avoid unnecessary delays. Before submitting, please read the terms and conditions of submissionand the declaration of competing interests. You may also like to use the Submission Checklist to help you prepare your paper.

4. Manuscript requirements

• Contributions must be typed in double spacing with wide margins. All sheets must be numbered.

• Manuscripts should be preceded by a title page which includes a full list of authors and their affiliations, as well as the corresponding author's contact details. You may like to use this template. When entering the author names into Editorial Manager, the corresponding author will be asked to provide a CRediT contributor role to classify the role that each author played in creating the manuscript. Please see the Project CRediT website for a list of roles.

• The main document must be anonymous. Please do not mention the authors' names or affiliations (including in the Method section) and refer to any previous work in the third person.

• Tables should be typed in double spacing, each on a separate page with a self-explanatory title. Tables should be comprehensible without reference to the text. They should be placed at the end of the manuscript but they must be mentioned in the text.

• Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form consistent with text use. Unnecessary background patterns, lines and shading should be avoided. Captions should be listed on a separate sheet. The resolution of digital images must be at least 300 dpi. All figures must be mentioned in the text.

• All papers must include a structured abstract of up to 250 words under the headings: Objectives, Methods, Results, Conclusions. Articles which report original scientific research should also include a heading 'Design' before 'Methods'. The 'Methods' section for systematic reviews and theoretical papers should include, as a minimum, a description of the methods the author(s) used to access the literature they drew upon. That is, the abstract should summarize the databases that were consulted and the search terms that were used.

• All Articles must include Practitioner Points – these are 2–4 bullet points to detail the positive clinical implications of the work, with a further 2–4 bullet points outlining cautions or limitations of the study. They should be placed below the abstract, with the heading ‘Practitioner Points’.
• For reference citations, please use APA style. Particular care should be taken to ensure that references are accurate and complete. Give all journal titles in full and provide DOI numbers where possible for journal articles.
• SI units must be used for all measurements, rounded off to practical values if appropriate, with the imperial equivalent in parentheses.
• In normal circumstances, effect size should be incorporated.
• Authors are requested to avoid the use of sexist language.
• Authors are responsible for acquiring written permission to publish lengthy quotations, illustrations, etc. for which they do not own copyright. For guidelines on editorial style, please consult the APA Publication Manual published by the American Psychological Association.

5. Brief reports and comments

These allow publication of research studies and theoretical, critical or review comments with an essential contribution to make. They should be limited to 2000 words, including references. The abstract should not exceed 120 words and should be structured under these headings: Objective, Method, Results, Conclusions. There should be no more than one table or figure, which should only be included if it conveys information more efficiently than the text. Title, author name and address are not included in the word limit.

6. Supporting Information

BJC is happy to accept articles with supporting information supplied for online only publication. This may include appendices, supplementary figures, sound files, videoclips etc. These will be posted on Wiley Online Library with the article. The print version will have a note indicating that extra material is available online. Please indicate clearly on submission which material is for online only publication. Please note that extra online only material is published as supplied by the author in the same file format and is not copyedited or typeset.

7. Copyright and licenses

If your paper is accepted, the author identified as the formal corresponding author for the paper will receive an email prompting them to login into Author Services, where via the

Wiley Author Licensing Service (WALS) they will be able to complete the license agreement on behalf of all authors on the paper.

For authors signing the copyright transfer agreement

If the OnlineOpen option is not selected the corresponding author will be presented with the copyright transfer agreement (CTA) to sign. The terms and conditions of the CTA can be previewed in the samples associated with the Copyright FAQs.

For authors choosing OnlineOpen

If the OnlineOpen option is selected the corresponding author will have a choice of the following Creative Commons License Open Access Agreements (OAA):

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If you select the OnlineOpen option and your research is funded by The Wellcome Trust and members of the Research Councils UK (RCUK) or the Austrian Science Fund (FWF) you will be given the opportunity to publish your article under a CC-BY license supporting you in complying with your Funder requirements.

8. Colour illustrations

Colour illustrations can be accepted for publication online. These would be reproduced in greyscale in the print version. If authors would like these figures to be reproduced in colour in print at their expense they should request this by completing a Colour Work Agreement form upon acceptance of the paper.

9. Pre-submission English-language editing

Authors for whom English is a second language may choose to have their manuscript professionally edited before submission to improve the English.

10. Author Services

Author Services enables authors to track their article – once it has been accepted – through the production process to publication online and in print. Authors can check the status of their articles online and choose to receive automated e-mails at key stages of production. The author will receive an e-mail with a unique link that enables them to register and have their article automatically added to the system. Please ensure that a complete e-mail address is provided when submitting the manuscript.

11. The Later Stages

The corresponding author will receive an email alert containing a link to a web site. A working e-mail address must therefore be provided for the corresponding author. The proof can be downloaded as a PDF (portable document format) file from this site. Acrobat Reader will be required in order to read this file.

This will enable the file to be opened, read on screen and annotated direct in the PDF. Corrections can also be supplied by hard copy if preferred. Further instructions will be sent with the proof. Excessive changes made by the author in the proofs, excluding typesetting errors, will be charged separately.

12. Early View

British Journal of Clinical Psychology is covered by the Early View service on Wiley Online Library. Early View articles are complete full-text articles published online in advance of their publication in a printed issue. Articles are therefore available as soon as they are ready, rather than having to wait for the next scheduled print issue. Early View articles are complete and final. They have been fully reviewed, revised and edited for publication, and the authors' final corrections have been incorporated. Because they are in final form, no changes can be made after online publication. The nature of Early View articles means that they do not yet have volume, issue or page numbers, so they cannot be cited in the traditional way. They are cited using their Digital Object Identifier (DOI) with no volume and issue or pagination information. E.g., Jones, A.B. (2010). Human rights Issues. *Human Rights Journal*. Advance online publication. doi:10.1111/j.1467-9299.2010.00300.x